TrialFinder- *recruiting interventional Trials*

Version 15.5.0
14.01.2026

	Solid tumors I		Solid tumors II		Hematological diseases
1	Bronchial cancer / Lung	14	Germ cell tumors	25	Leukemias
2	Head and neck tumors	15	Sarcomas	26	Myeloproliferative neoplasms (MPN)
3	Esophageal cancer	16	Hepatocellular cancer	27	Mastocytosis
4	Gastric cancer and gastro-Esophageal junction	17	Renal cell cancer	28	Hodgkin's disease
5	Pancreatic cancer	18	Skin tumors	29	Non-Hodgkin's lymphoma/ Waldenström's disease
6	Cholangiocellular carcinoma	19	Brain tumors	30	Multiple Myeloma
7	Small bowel cancer	20	GIST tumors	31	Myelodysplastic syndrome (MDS)
8	Colorectal cancer/ Colon			32	Anemia
9	Urothelial bladder cancer	21	Side effects of oncological therapies	33	Immune thrombocytopenia (ITP)
10	Prostate cancer	22	Paediatric Oncology & Hematology	34	Amyloidosis
11	Neuroendocrine tumors	23	Cross-entity studies (Basket studies)	35	Primary CNS lymphomas (PCNSL)
12	Breast cancer	24	Cellular therapies		
13	Gynecological tumors				

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continue...

TrialFinder

This linked document provides you with a comprehensive collection of all interventional studies currently underway in our network, including those of our partners at UCC Hamburg and UCC SH.
The links will take you to the institutions with the inclusion criteria for the individual studies (Trial Pathways path).
Further information can be found via the links provided.

The respective principal investigator (PI) is responsible for the accuracy of the study information.

For any suggestions, additions or corrections please contact:

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Lead clinical research *UCC Hamburg*	*PD Dr. med. MBA*	*Andreas Block*	*E-Mail: block@uke.de*

Quellen:
euclinicaltrials.eu
clinicaltrials.gov
Drks.de
Dpcg.nl

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Please also check the possibility of inclusion in the BASKET studies!

Bronchial cancer / Lung

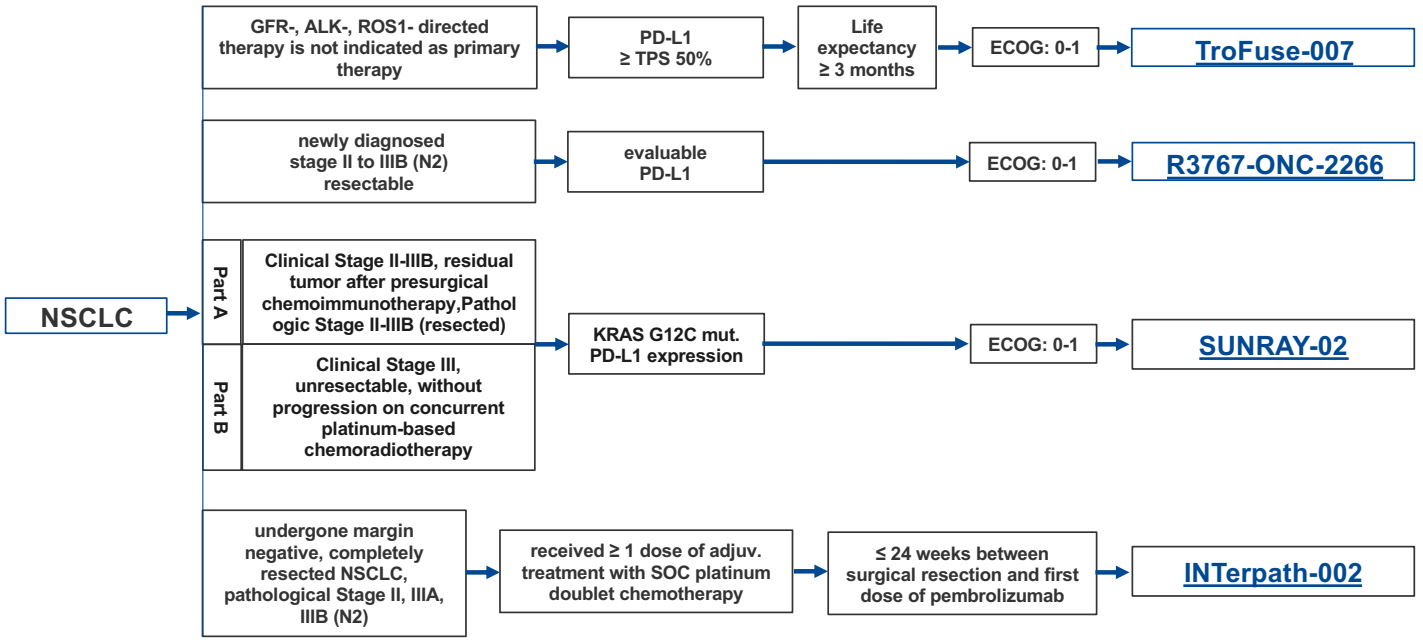
1a NSCLC

1b SCLC

1b Pleural Mesothelioma

Contact at UCC Hamburg
PD Dr. med. Maximilian Christopeit, Tel.: 040-7410-51384

1a Trial pathways / *Bronchial cancer* / NSCLC



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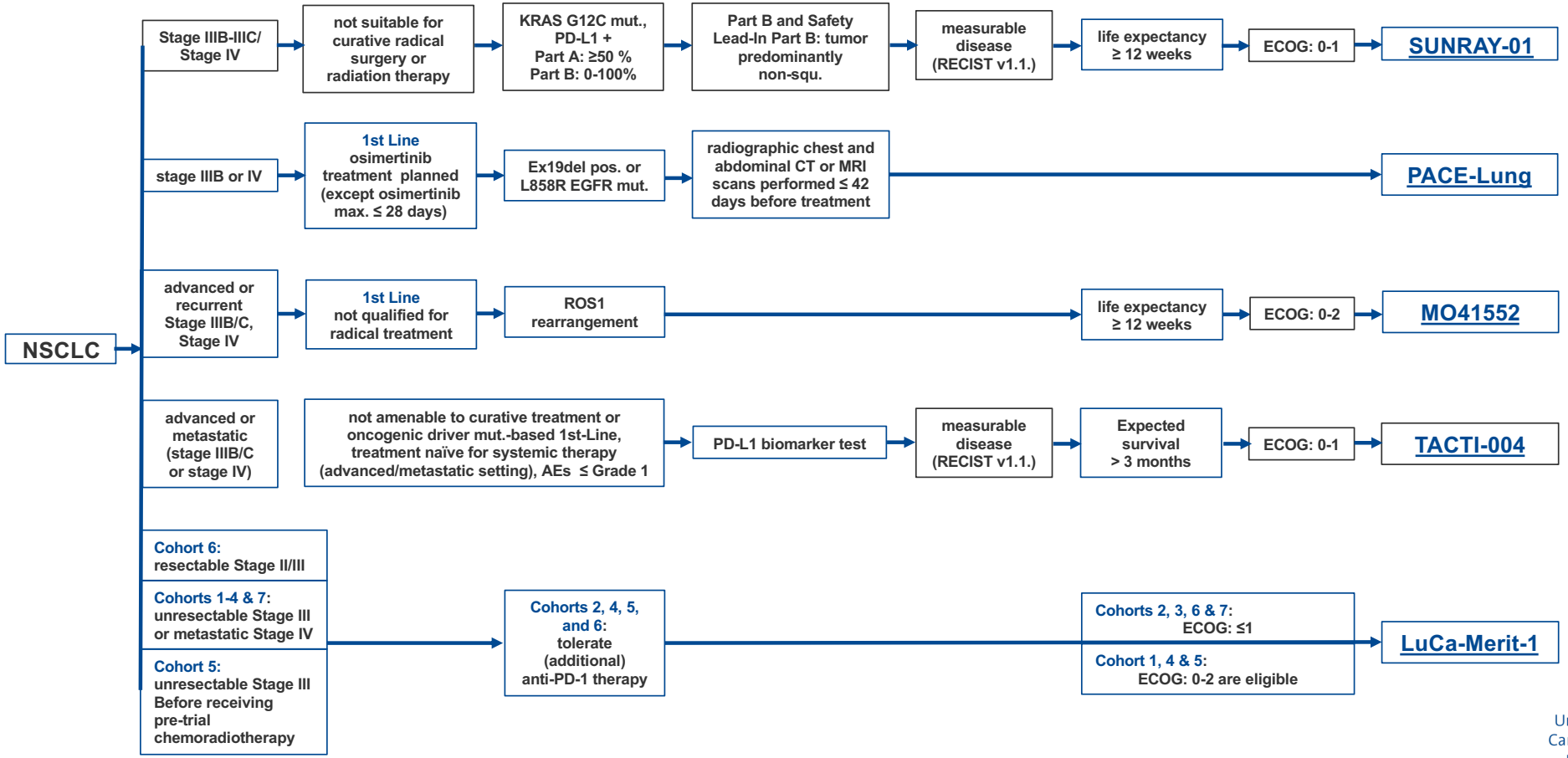
Please also check the possibility of inclusion in the BASKET studies!

1a Trial pathways / *Bronchial cancer / NSCLC*



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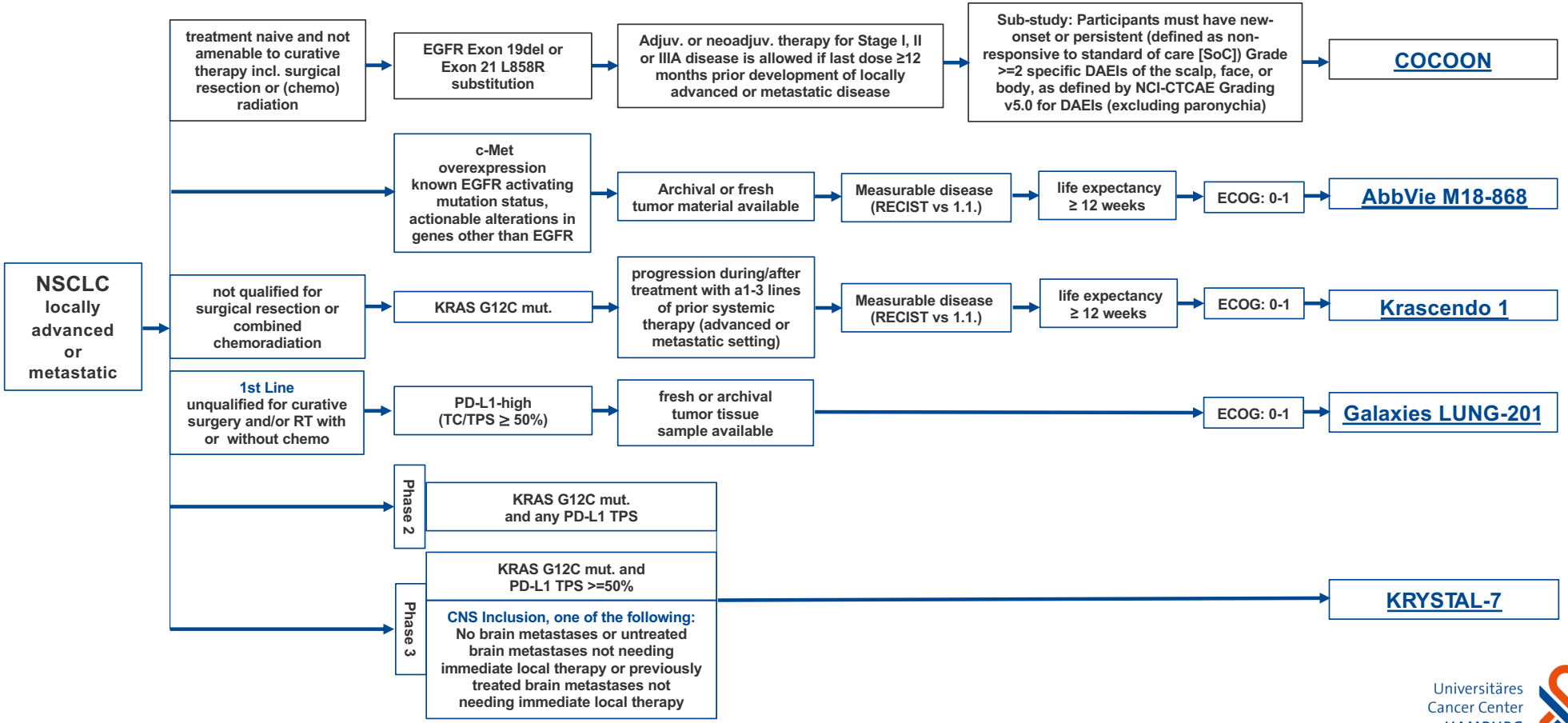
Please also check the possibility of inclusion in the BASKET studies!

1a Trial pathways / *Bronchial cancer / NSCLC*



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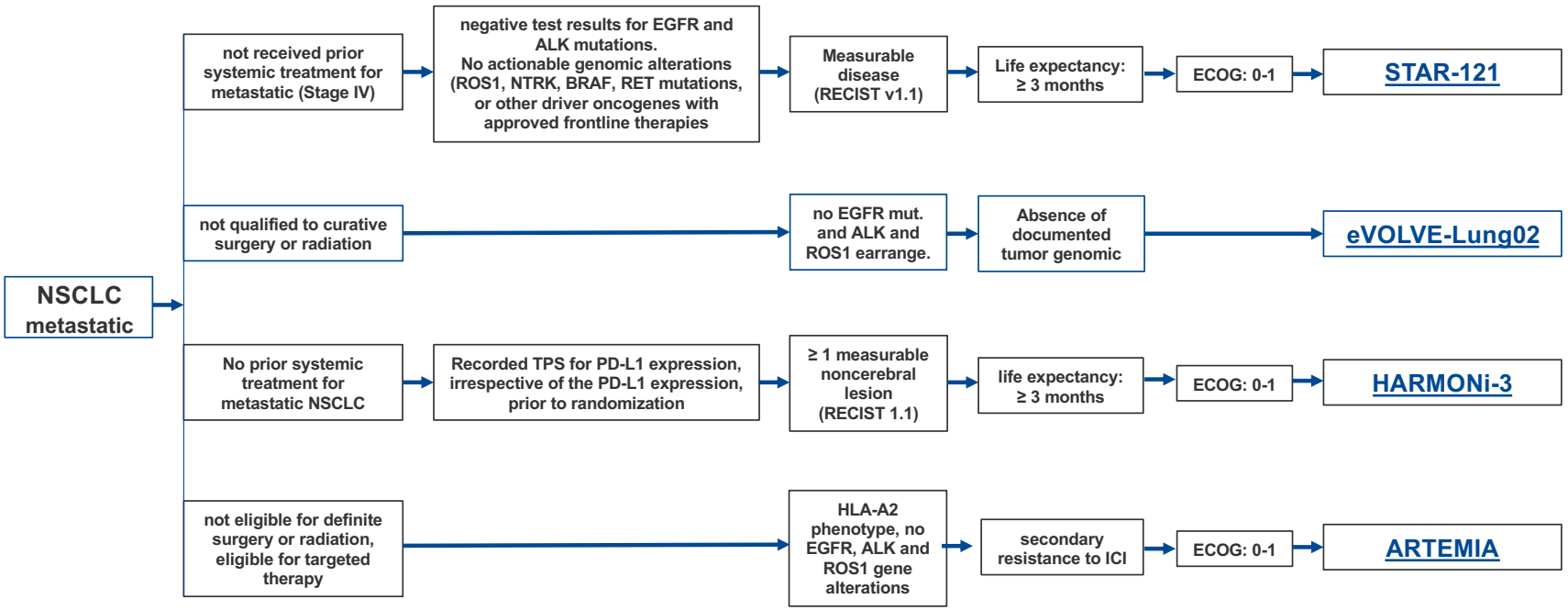
Please also check the possibility of inclusion in the BASKET studies!

1a Trial pathways / *Bronchial cancer / NSCLC*



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Please also check the possibility of inclusion in the BASKET studies!

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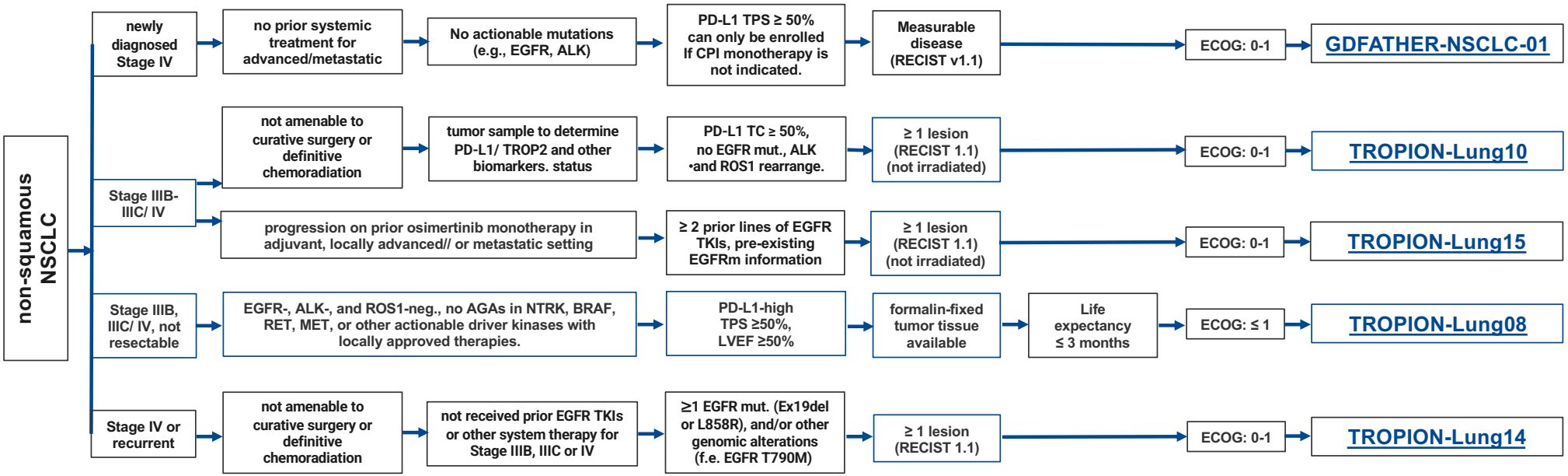
1a Trial pathways / *Bronchial cancer / NSCLC non-squamous*



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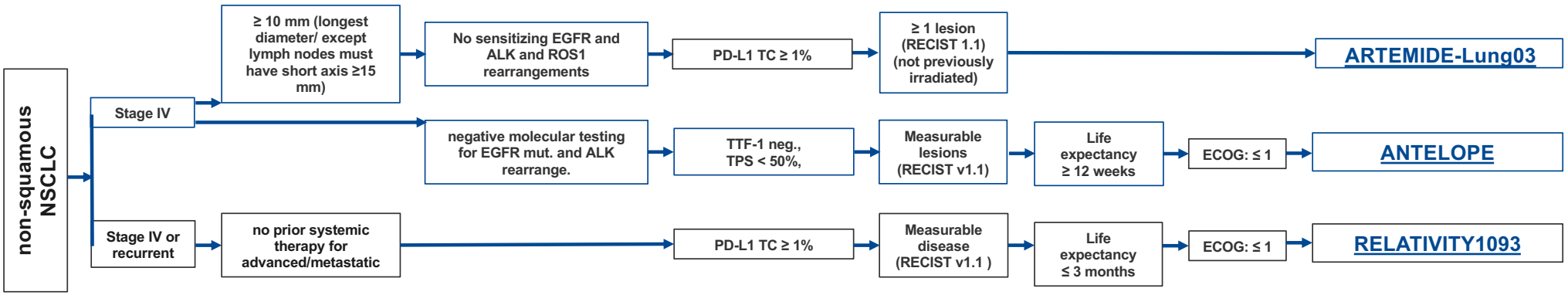
Please also check the possibility of inclusion in the BASKET studies!

1a Trial pathways / *Bronchial cancer* / NSCLC non-squamous



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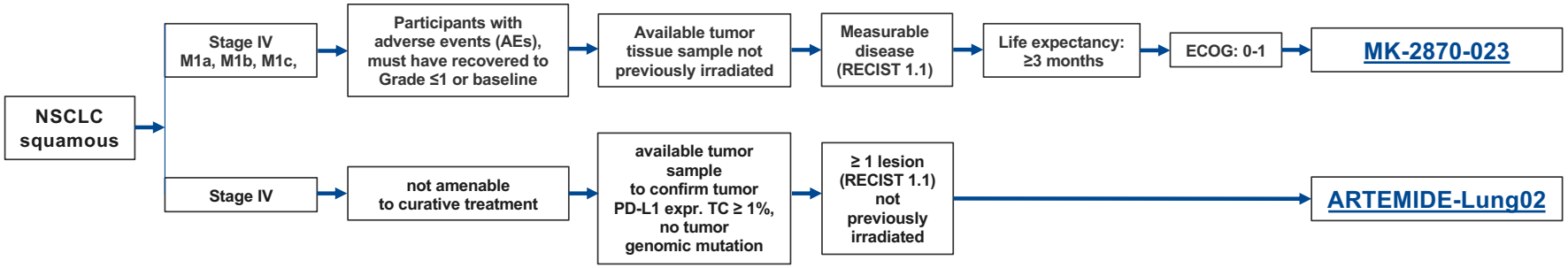
Please also check the possibility of inclusion in the BASKET studies!

1a Trial pathways / *Bronchial cancer* / NSCLC squamous



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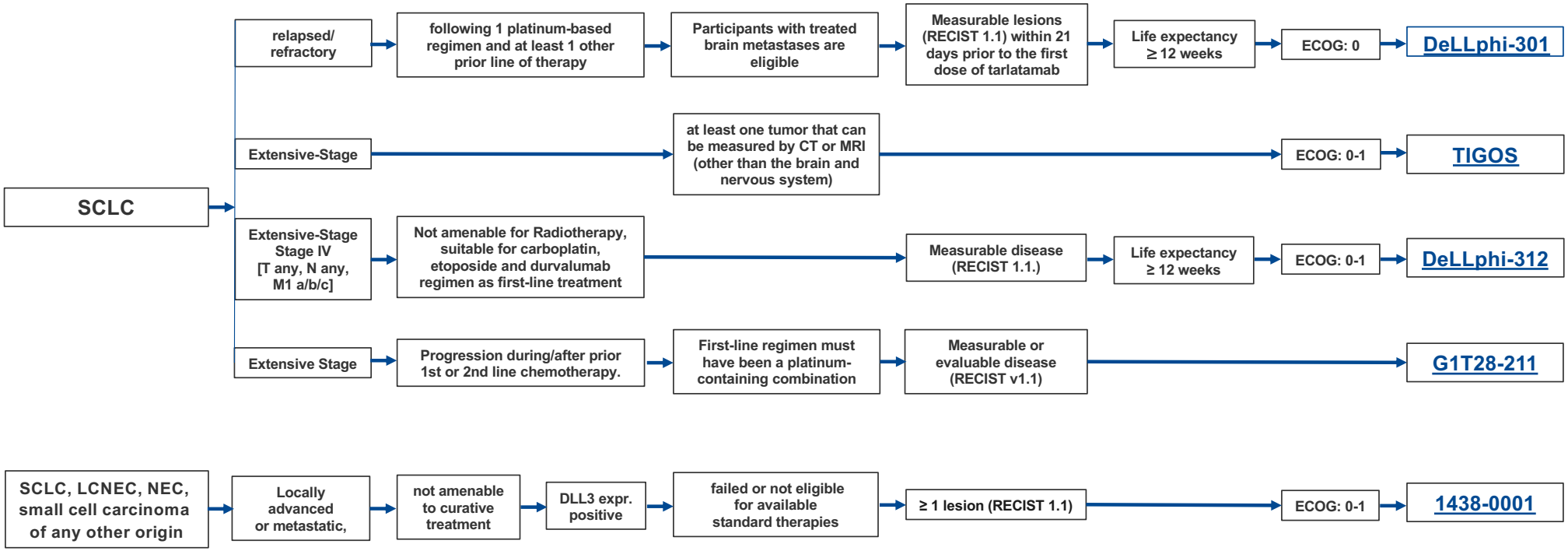
Please also check the possibility of inclusion in the BASKET studies!

1b Trial pathways / *Bronchial cancer / SCLC*



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Please also check the possibility of inclusion in the BASKET studies!

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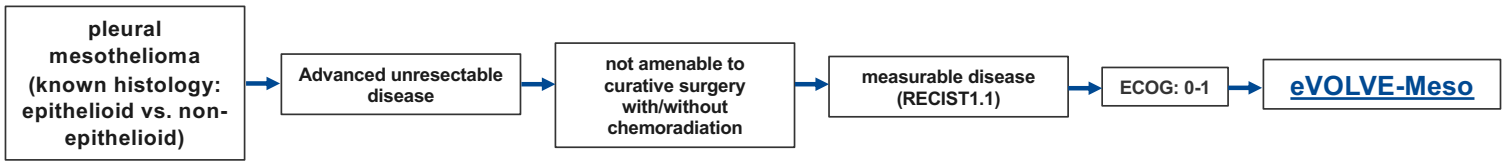
1c Trial pathways / *Bronchial cancer / Pleural Mesothelioma*



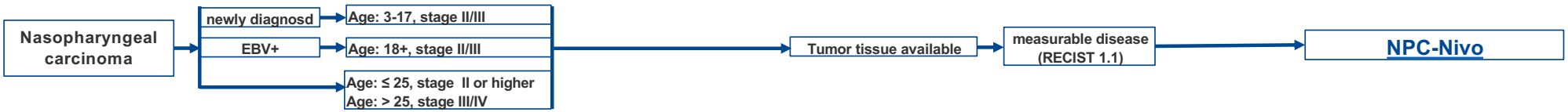
Please also check the possibility of inclusion in the BASKET studies!

Head and neck tumors

continue...

Contact at UCC Hamburg
Dr. med. Philippe Schafhausen, Tel.: 040-7410-57122

2 Trial pathways / *Head and neck tumors*



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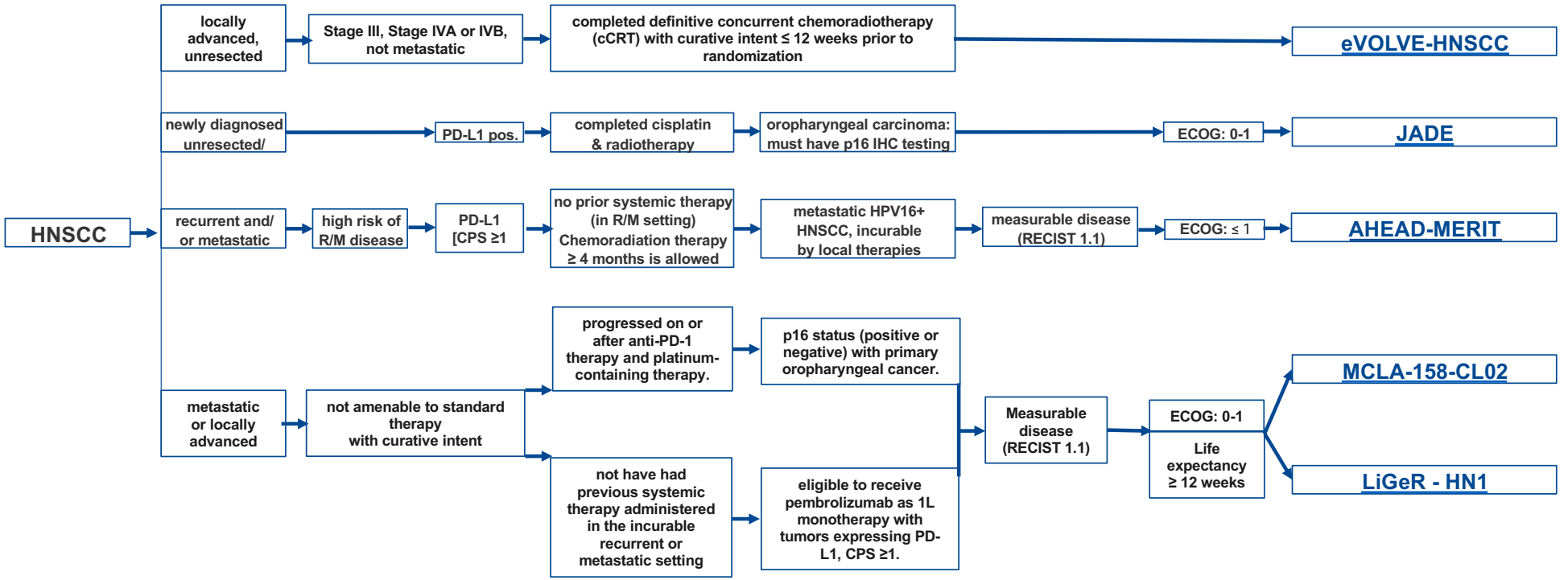
Please also check the possibility of inclusion in the BASKET studies!

2 Trial pathways / *Head and neck tumors*



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Please also check the possibility of inclusion in the BASKET studies!

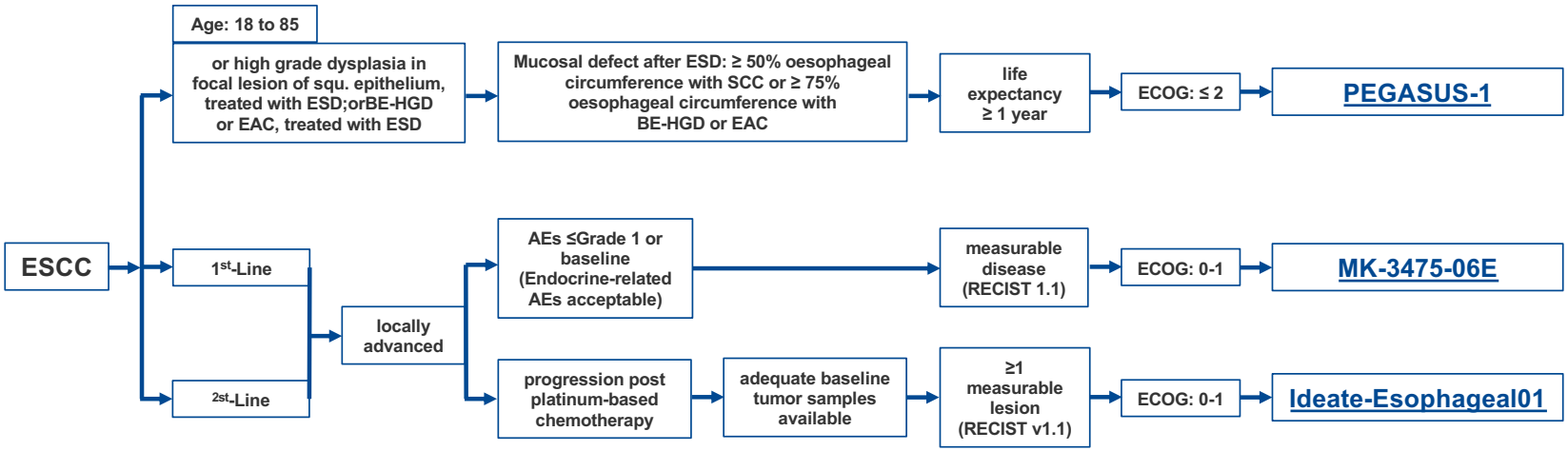
Esophageal cancer

3a Oesophagus-unresectable or metastatic

3b Oesophagus + gastroesophageal junction - resectable

Contact at UCC Hamburg
PD Dr. med. Marianne Sinn, Tel.: 040-7410-56882

3a Trial pathways / *Esophagus - unresectable or metastatic*



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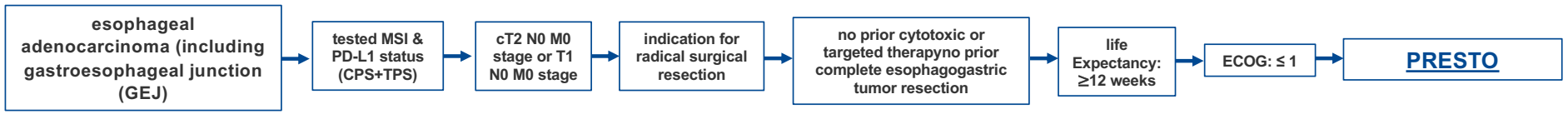
Please also check the possibility of inclusion in the BASKET studies!

3b Trial pathways / *Oesophagus + gastrooesoph. junction - resectable*



Please also check the possibility of inclusion in the BASKET studies!

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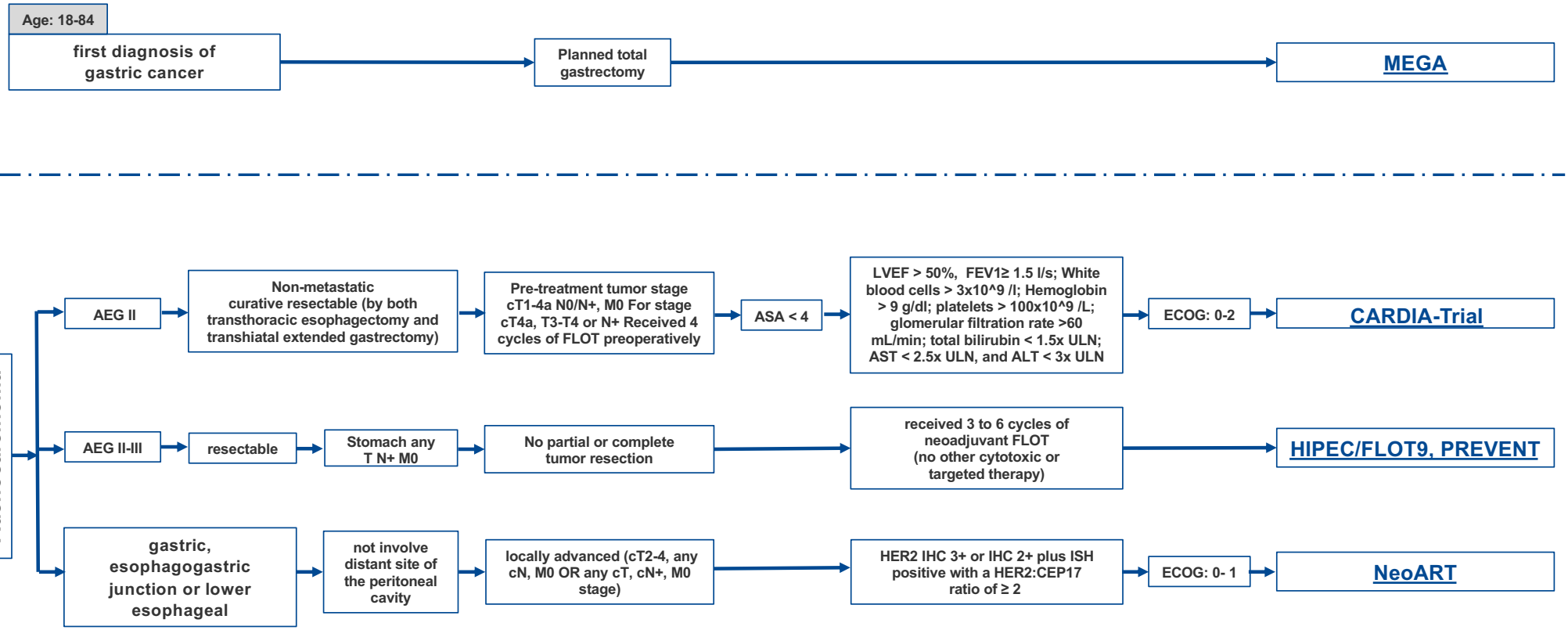
Gastric cancer and gastroesophageal junction

4a resectable

4b unresectable

Contact at UCC Hamburg
PD Dr. med. Marianne Sinn, Tel.: 040-7410-56882

4a Trial pathways / *Gastric and gastroesophageal junction (resectable)*



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Please also check the possibility of inclusion in the BASKET studies!

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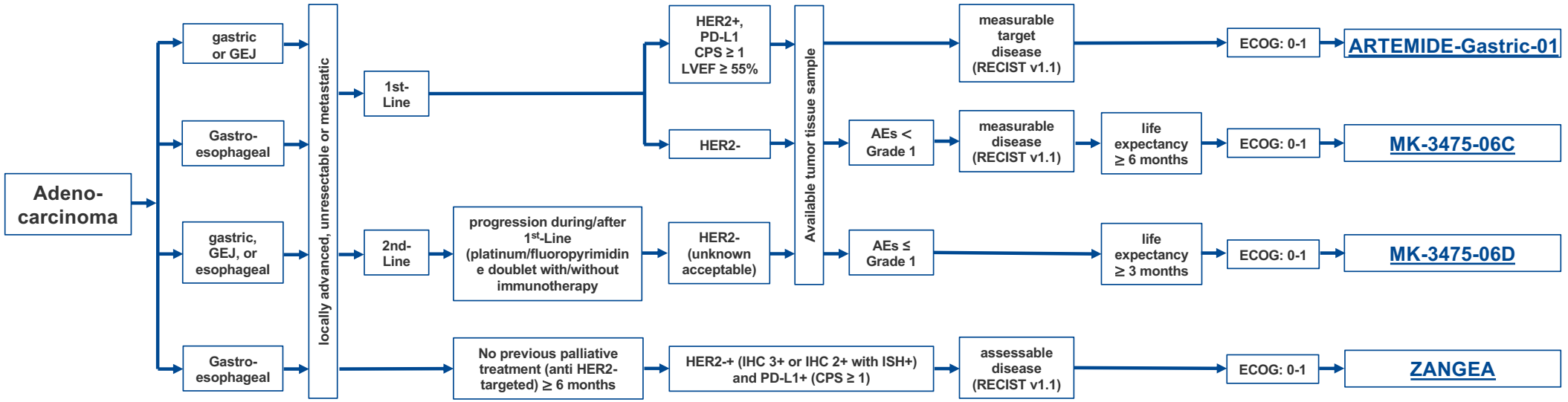
4b Trial pathways / *Gastric and gastroesophageal junction (unresectable)*



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Please also check the possibility of inclusion in the BASKET studies!

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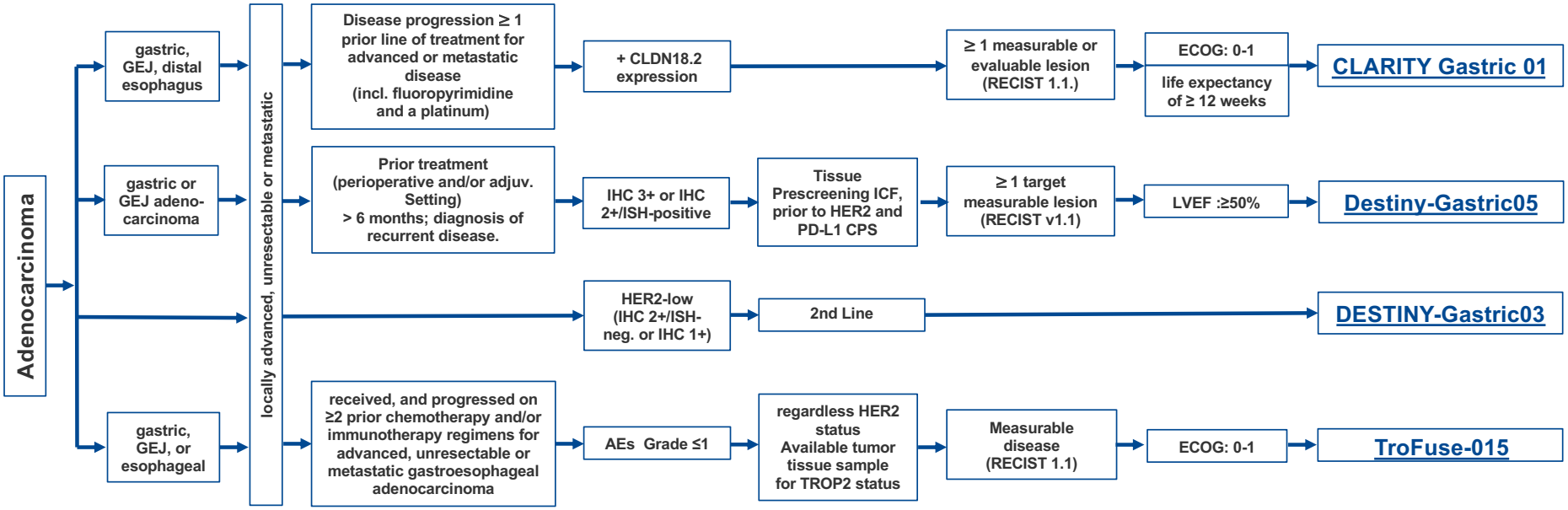
4b Trial pathways / *Gastric and gastroesophageal junction (unresectable)*



Please also check the possibility of inclusion in the BASKET studies!

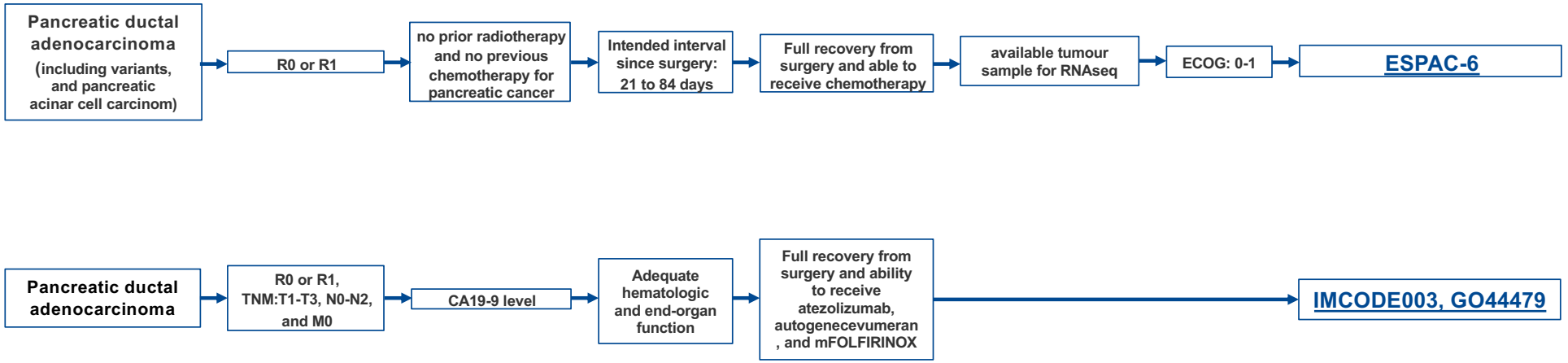
Pancreatic cancer

5a localised

5b metastatic

Contact at UCC Hamburg
PD Dr. med. Marianne Sinn, Tel.: 040-7410-56882
PD Dr. med. Andreas Block, MBA, 040 7410-56305

5a Trial pathways / *Pancreatic cancer (localized)*



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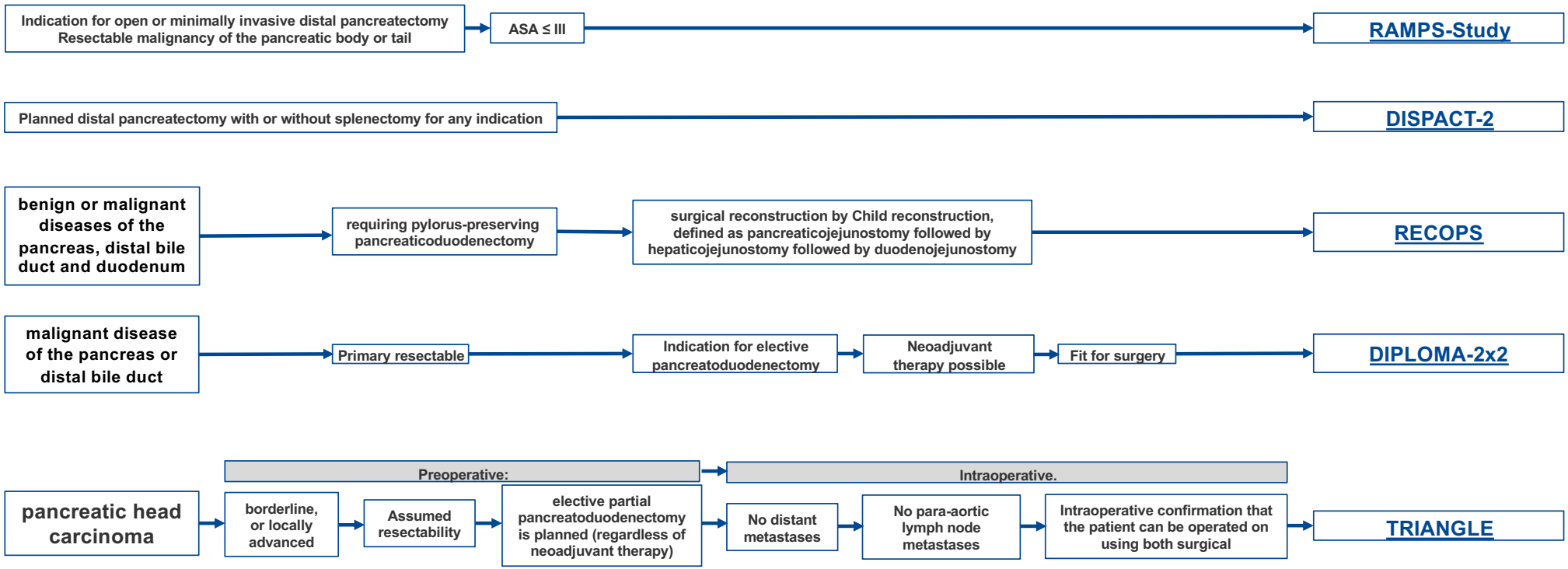
Please also check the possibility of inclusion in the BASKET studies!

5a Trial pathways / *Pancreatic cancer (localized)*



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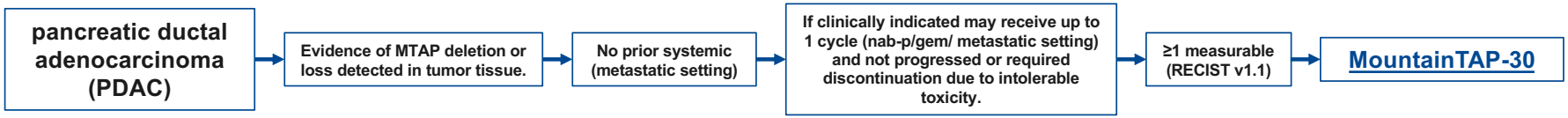
Please also check the possibility of inclusion in the BASKET studies!

5b Trial pathways / *Pancreatic cancer (metastatic)*



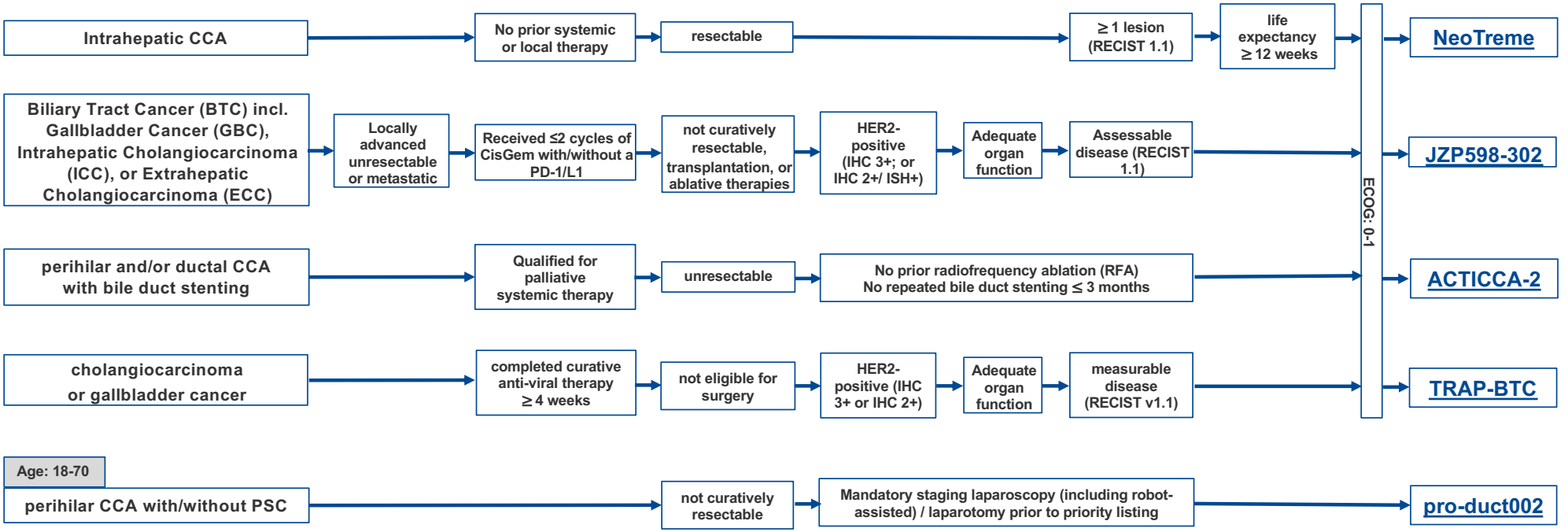
Please also check the possibility of inclusion in the BASKET studies!

Cholangiocellular carcinoma

continue...

Contact at UCC Hamburg
PD Dr. med. Marianne Sinn, Tel.: 040-7410-56882
PD Dr. med. Kornelius Schulze, Tel.: 0152 22817169

6 Trial pathways / *Cholangiocellular carcinoma*



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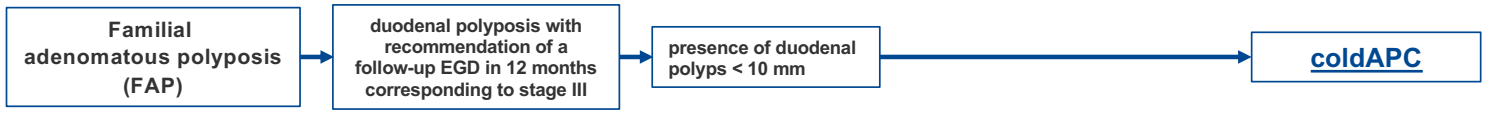
Please also check the possibility of inclusion in the BASKET studies!

Small bowel cancer

continue...

Contact at UCC Hamburg
PD Dr. med. Marianne Sinn, Tel.: 040-7410-56882

7 Trial pathways / *Small bowel cancer*



Please also check the possibility of inclusion in the BASKET studies!

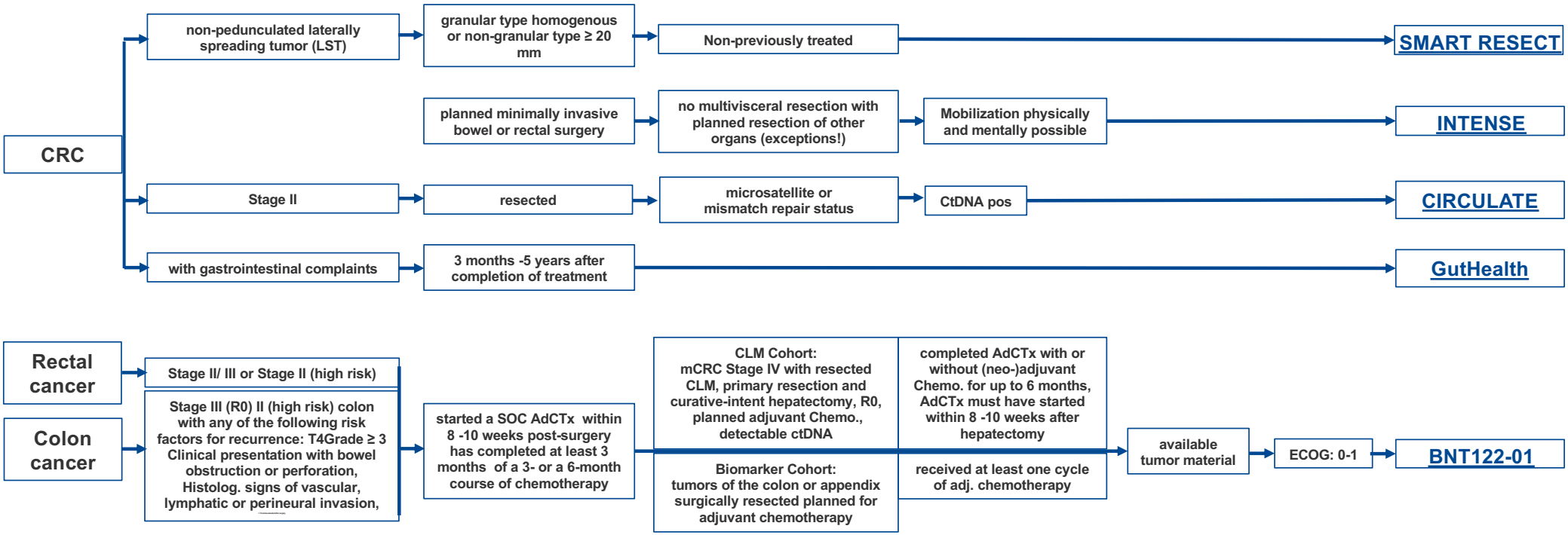
Colorectal cancer/ Colon

8a localized

8b metastatic

Contact at UCC Hamburg
PD Dr. med. Marianne Sinn, Tel.: 040-7410-56882

8a Trial pathways / *Colorectal cancer (localized)*



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Please also check the possibility of inclusion in the BASKET studies!

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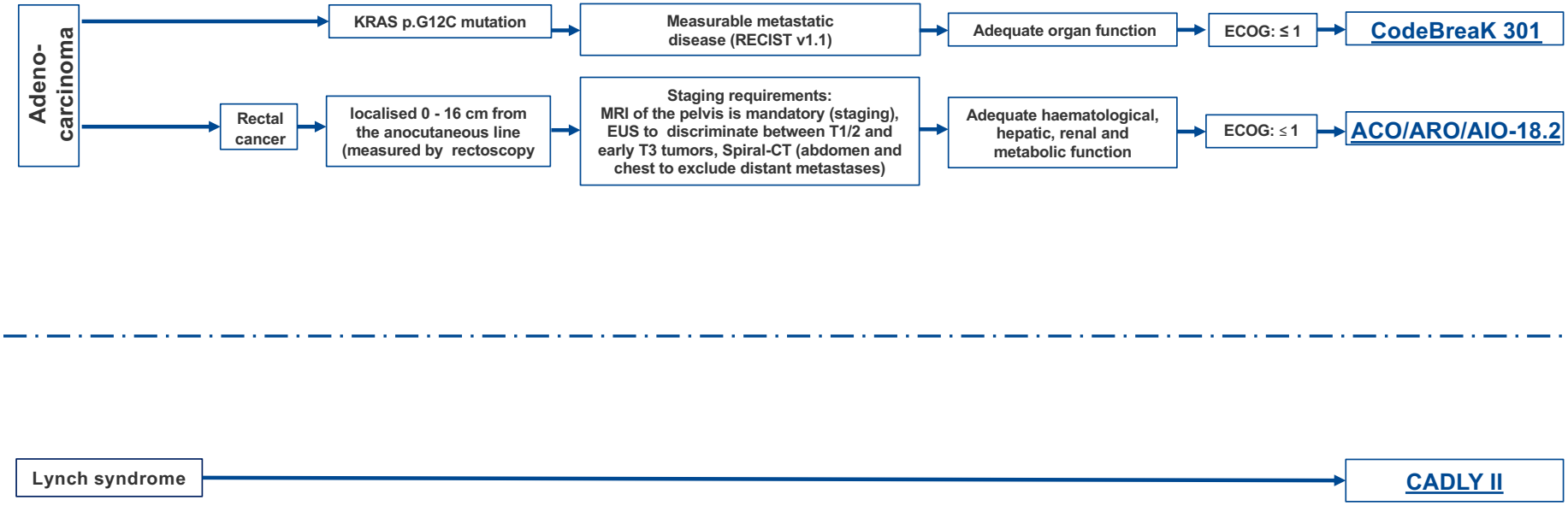
8a Trial pathways / *Colorectal cancer (localized)*



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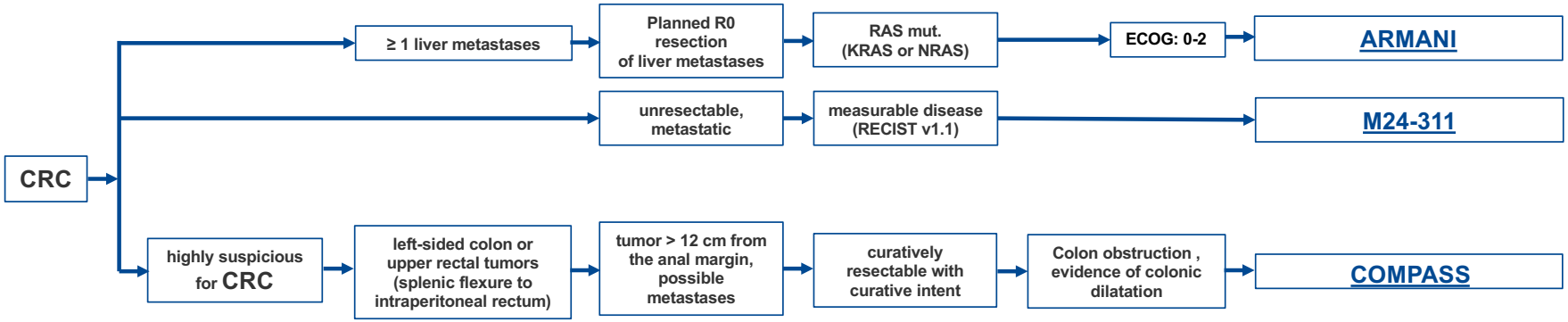
Please also check the possibility of inclusion in the BASKET studies!

8b Trial pathways / *Colorectal cancer (metastatic)*



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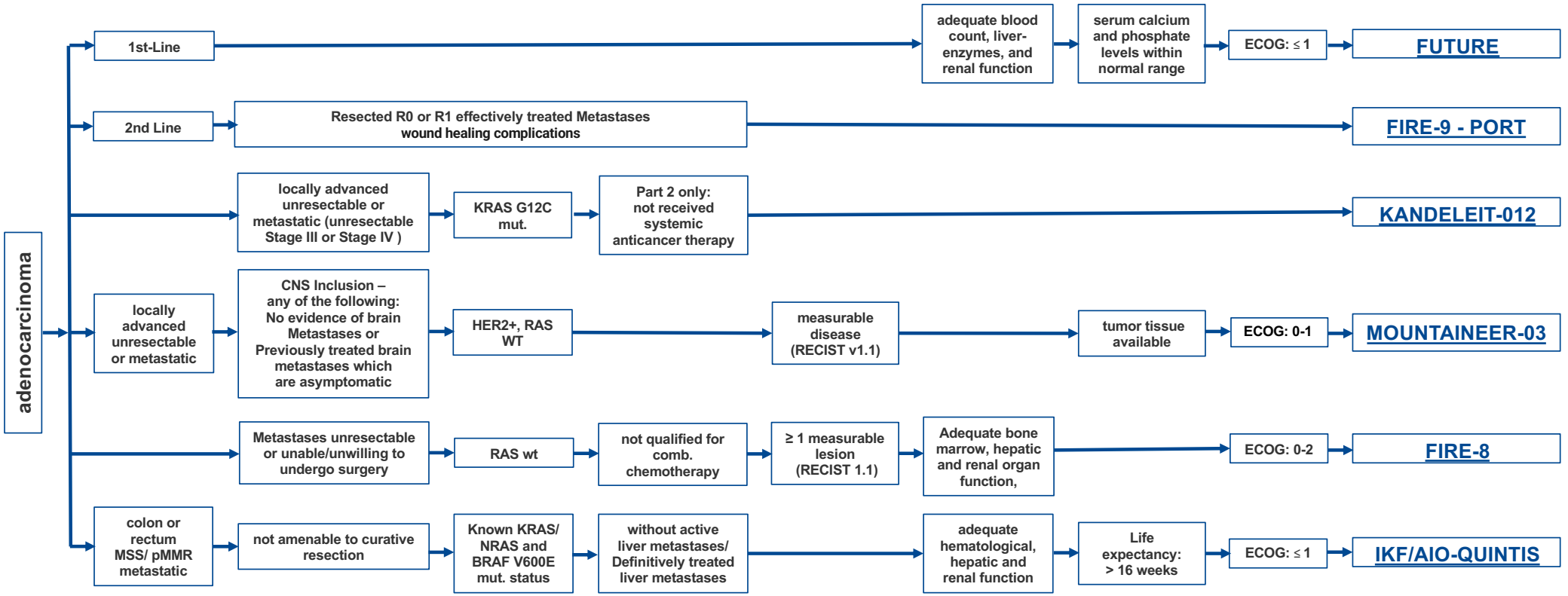
Please also check the possibility of inclusion in the BASKET studies!

8b Trial pathways / *Colorectal cancer (metastatic)*



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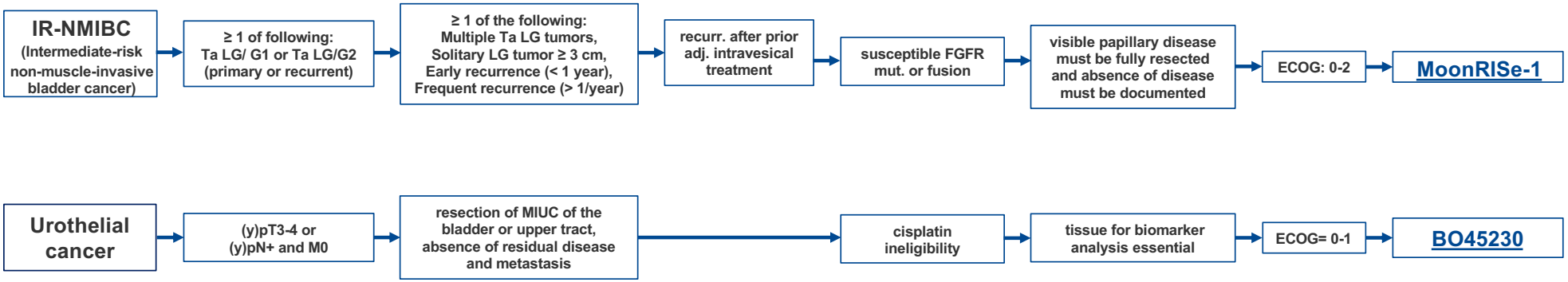
Please also check the possibility of inclusion in the BASKET studies!

Urothelial bladder cancer

continue...

Contact at UCC Hamburg
Prof. Dr. med. Gunhild von Amsberg, Tel.: 0152-22815585

9 Trial pathways / *Urothelial bladder cancer*



Please also check the possibility of inclusion in the BASKET studies!

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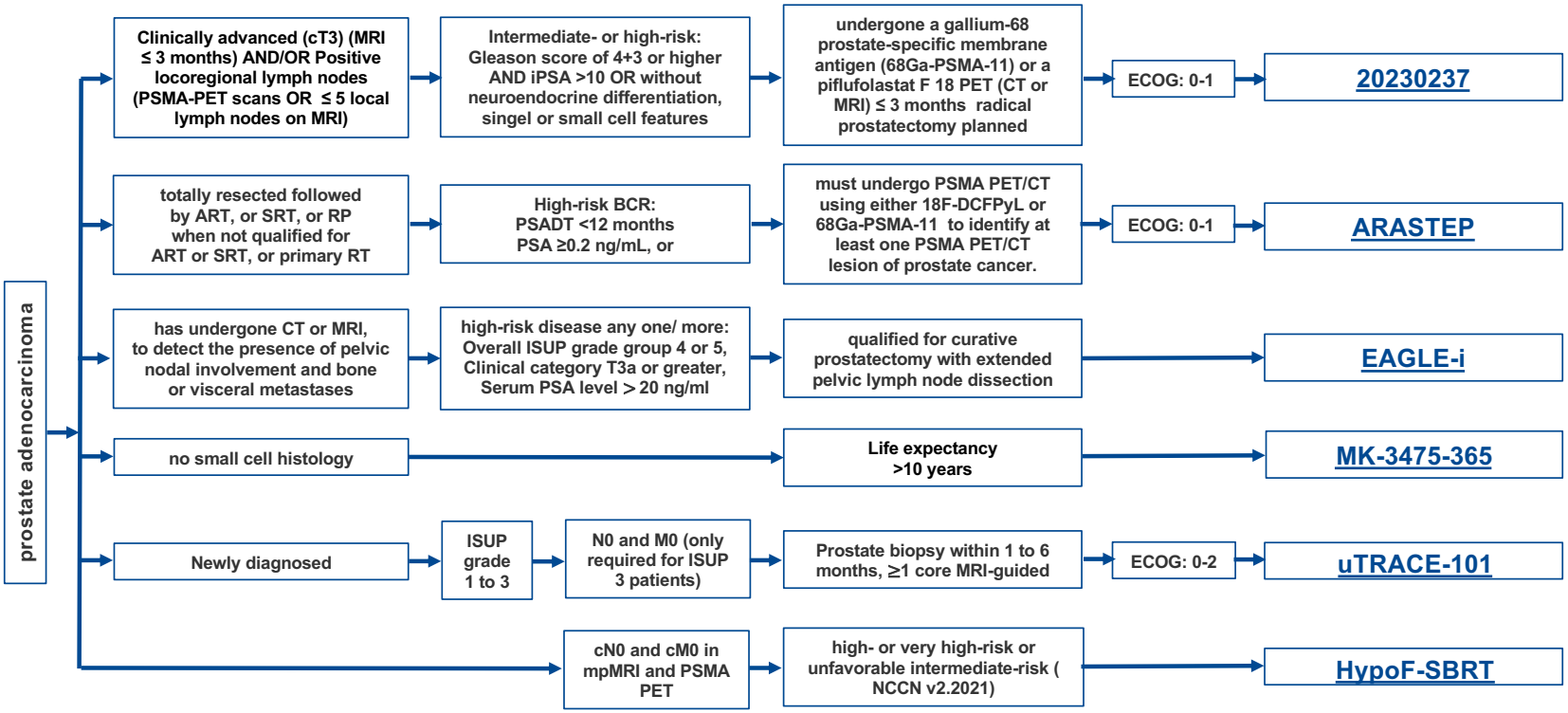
Prostate cancer

10a localized

10b metastatic

Contact at UCC Hamburg
Prof. Dr. med. Gunhild von Amsberg, Tel.: 0152-22815585

10a Trial pathways / *Prostate cancer (localized)*



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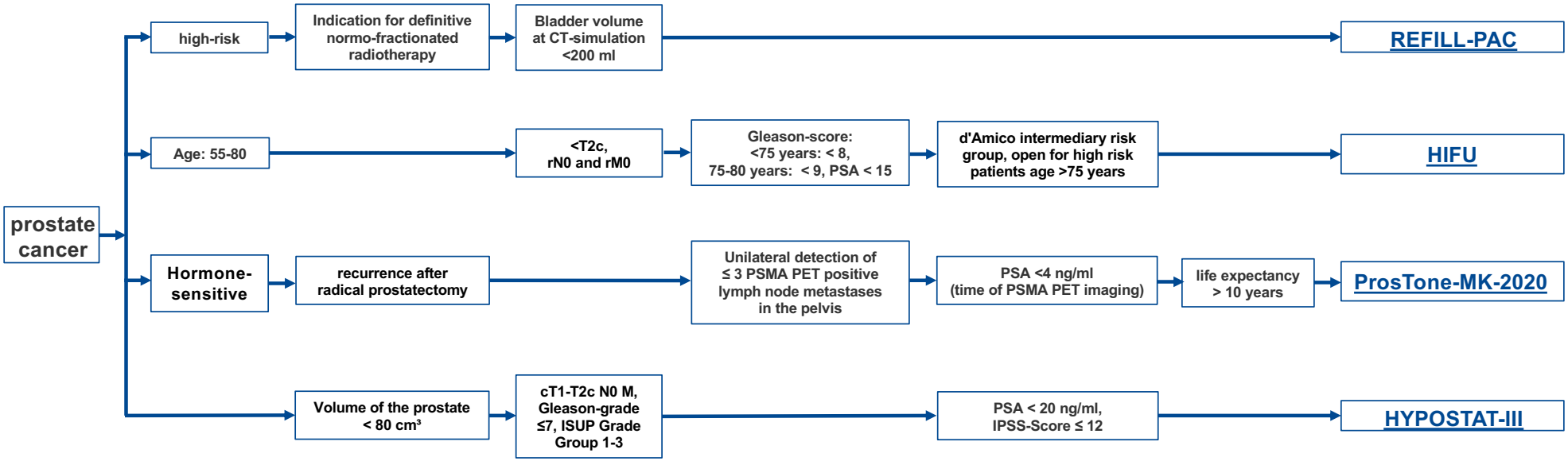
Please also check the possibility of inclusion in the BASKET studies!

10a Trial pathways / *Prostate cancer (localized)*



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Please also check the possibility of inclusion in the BASKET studies!

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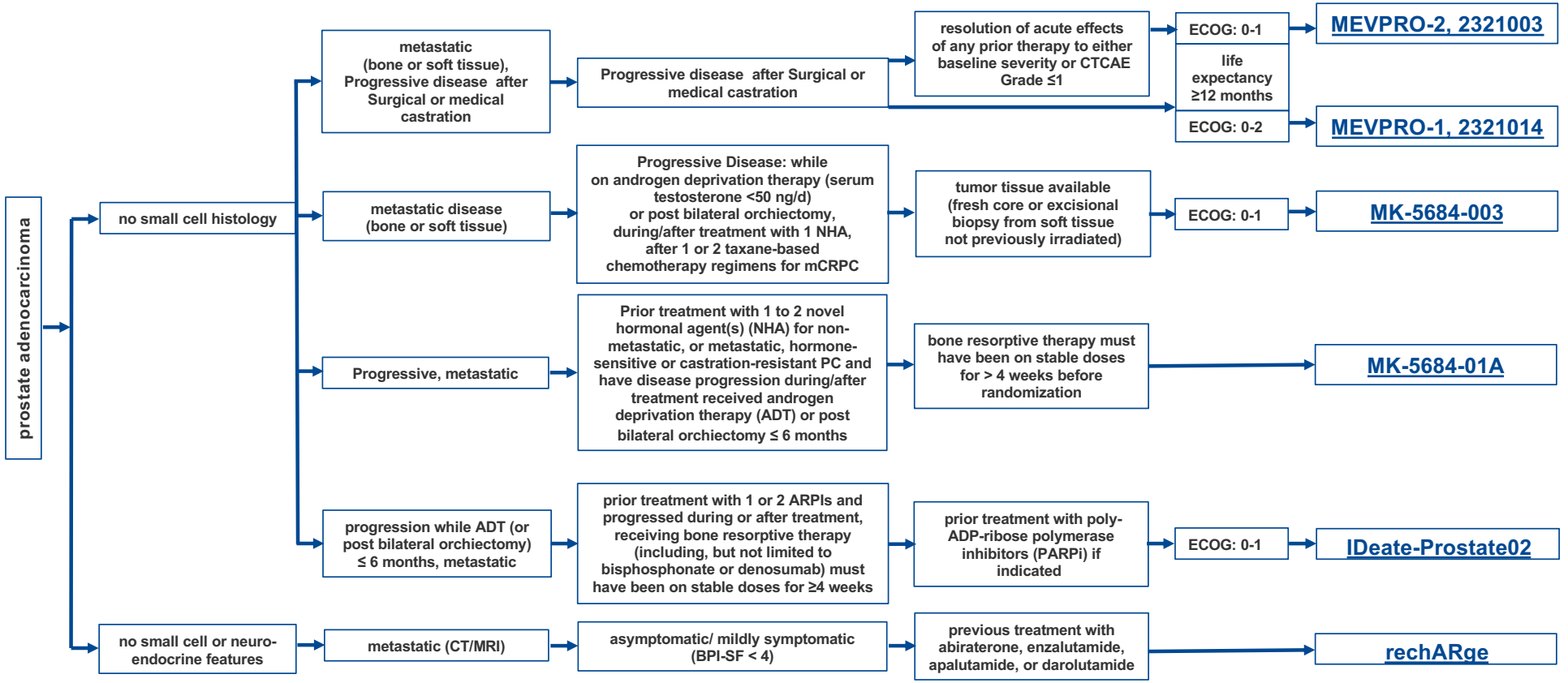
10b Trial pathways / *Prostate cancer (metastatic)*



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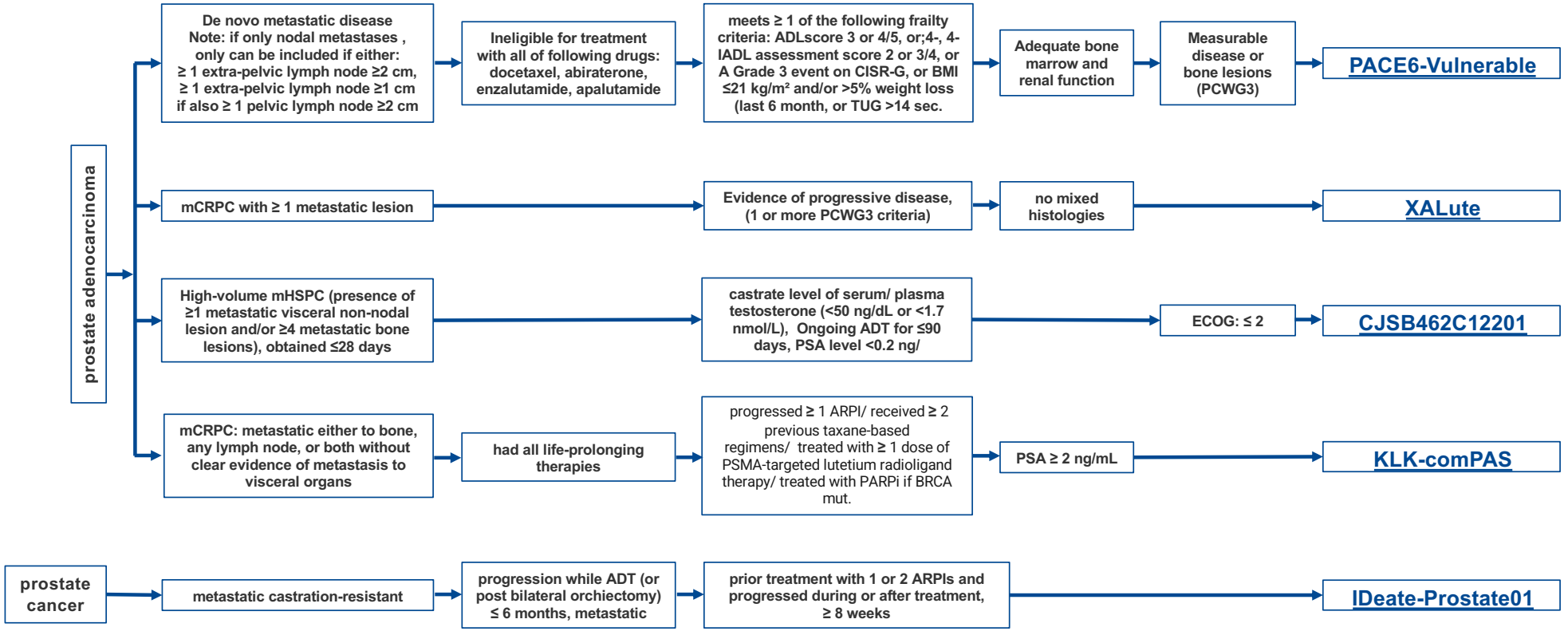
Please also check the possibility of inclusion in the BASKET studies!

10b Trial pathways / *Prostate cancer (metastatic)*



Please also check the possibility of inclusion in the BASKET studies!

Neuroendocrine tumors

continue...

Contact at UCC Hamburg
PD Dr. med. Anna Nießen, Tel.: 015222842074
Dr. med. Thorben W. Fründt, Tel.: 040 7410-18056

Currently no study options

Please also check the possibility of inclusion in the BASKET studies!

Breast cancer

- 12a Preventive
- 12b localized
- 12c metastatic

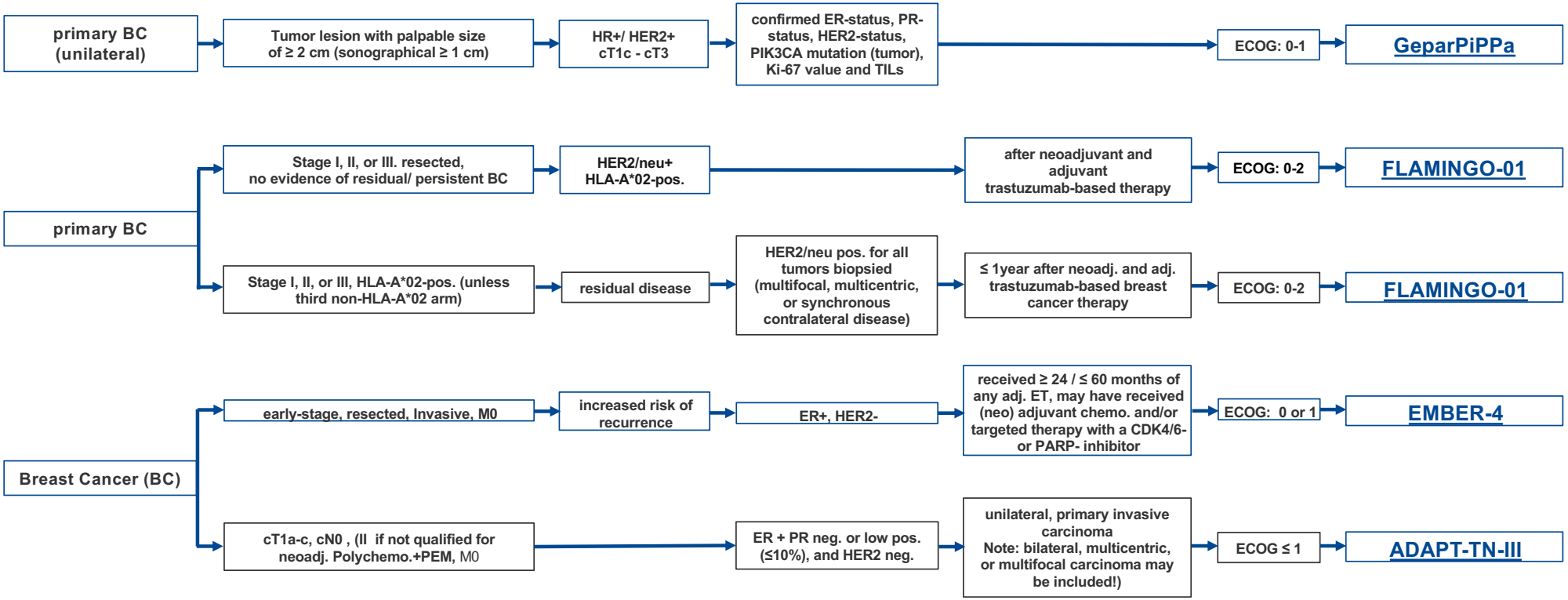
Contact at UCC Hamburg
Prof. Dr. med. Volkmar Müller, Tel.: 040 7410-52510

Currently no study options

continue...

Please also check the possibility of inclusion in the BASKET studies!

12b Trial pathways / *Breast cancer (localized)*



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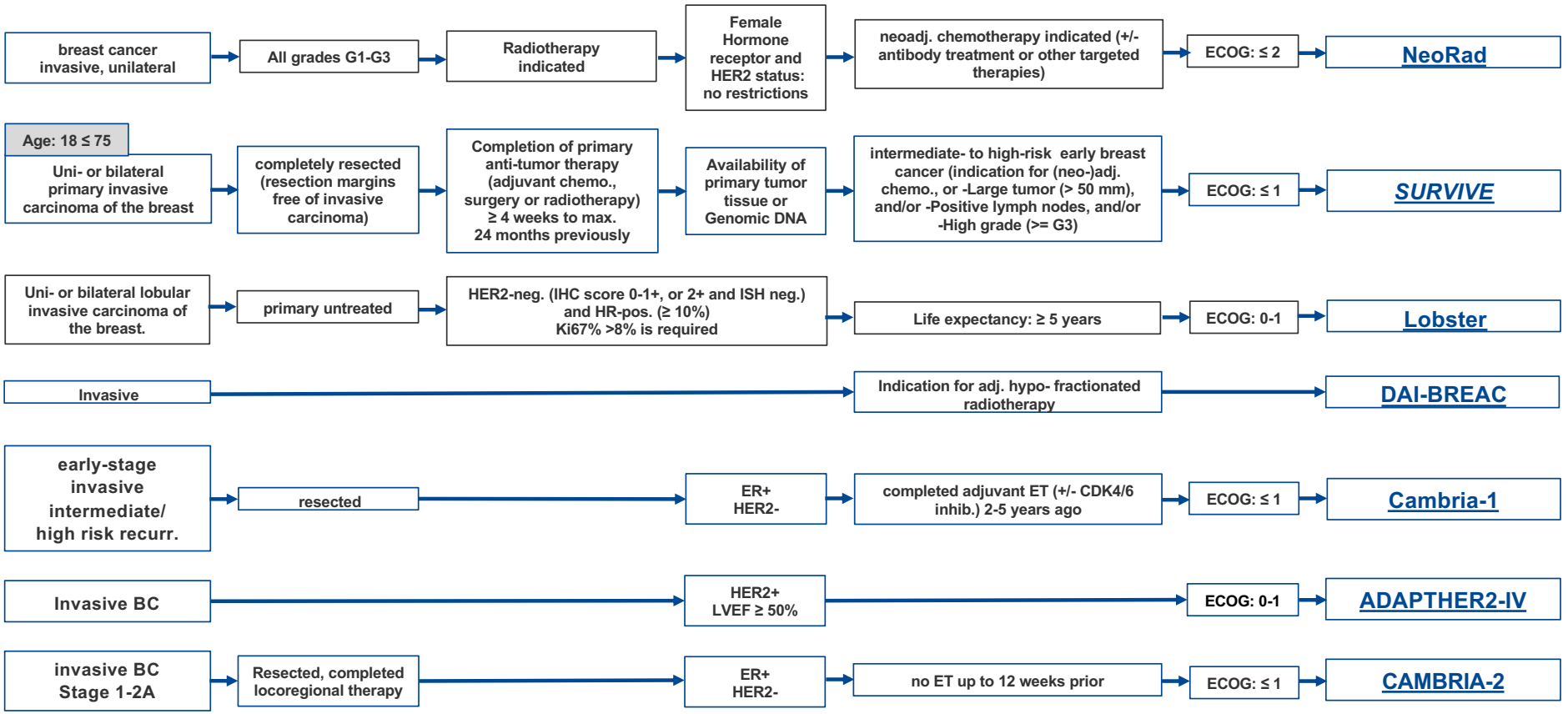
Please also check the possibility of inclusion in the BASKET studies!

12b Trial pathways / *Breast cancer (localized)*



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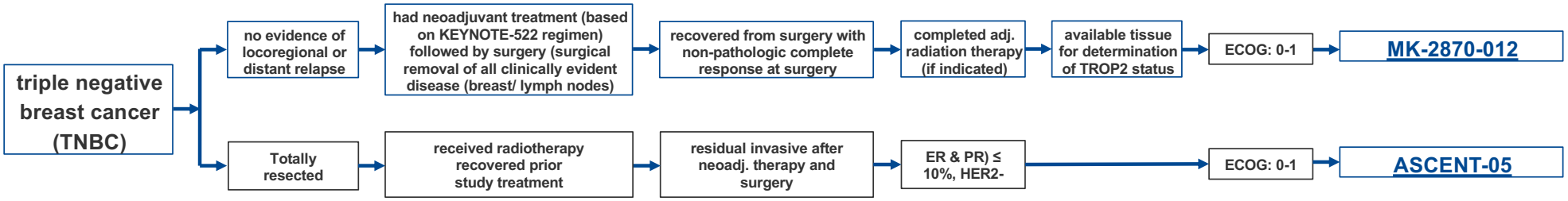
Please also check the possibility of inclusion in the BASKET studies!

12b Trial pathways / *Breast cancer (localized)*



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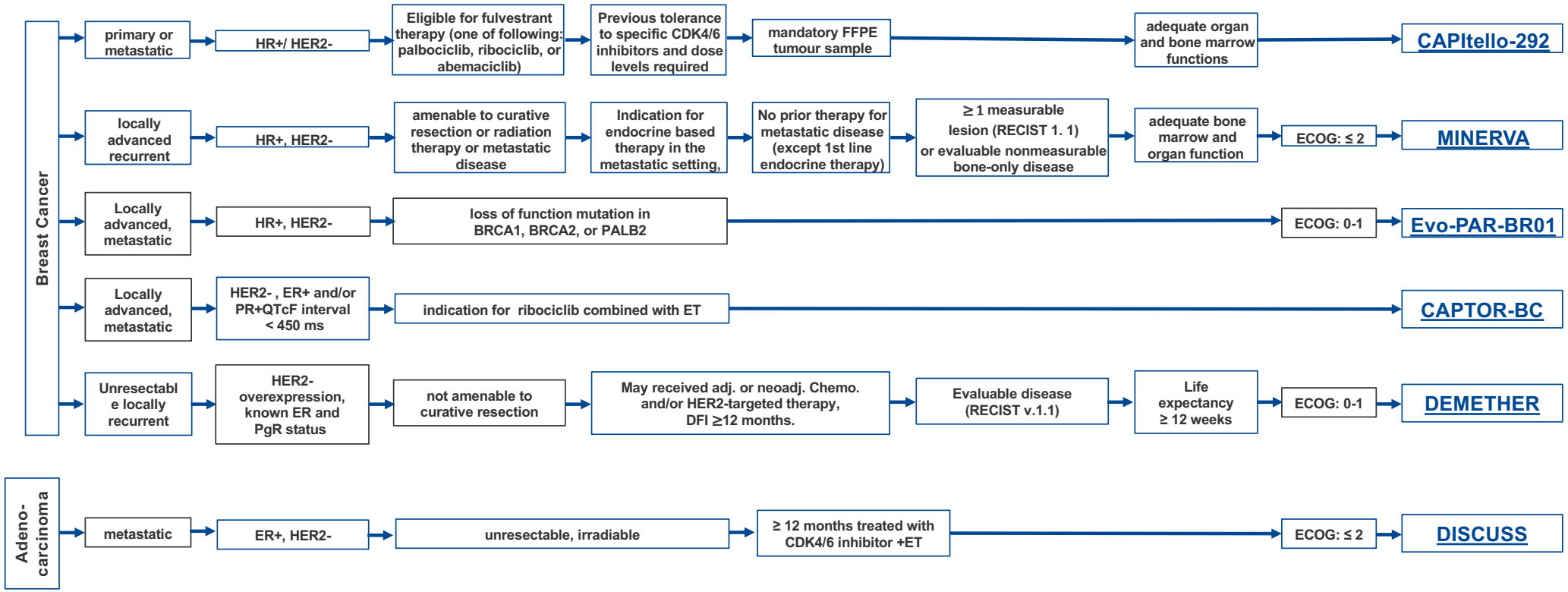
Please also check the possibility of inclusion in the BASKET studies!

12c Trial pathways / *Breast cancer (metastatic)*



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Please also check the possibility of inclusion in the BASKET studies!

Gynecological tumors

13a Ovarian cancer

13b Cervical cancer

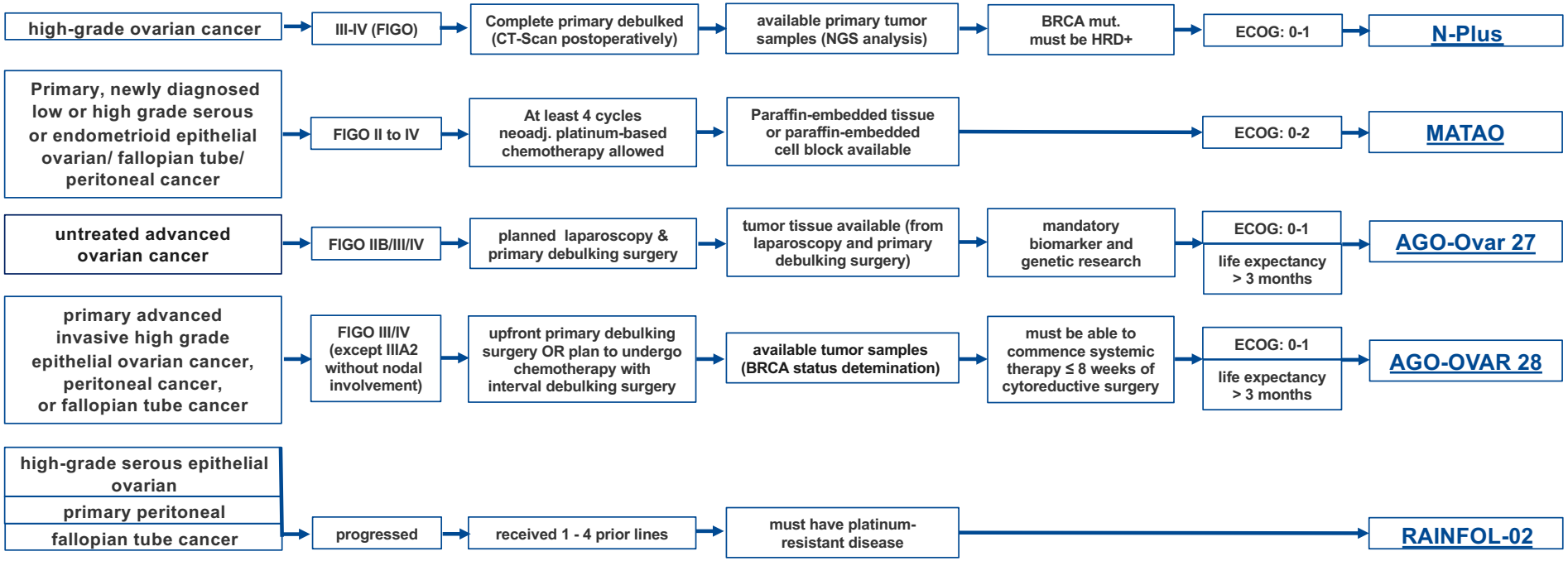
13c Endometrial cancer

13d Vulva cancer

Contact at UCC Hamburg
Prof. Dr. med. Volkmar Müller, Tel.: 040 7410-52510

Contact at UCC Mammazentrum HH
Silke Kassner, Tel.: 040 44190 669

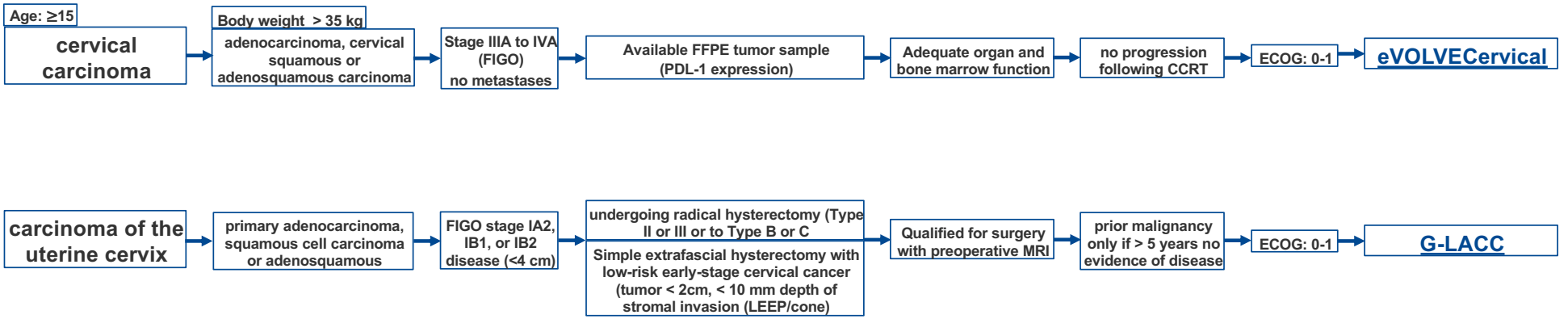
13a Trial pathways / *Ovarian cancer*



continue...

Please also check the possibility of inclusion in the BASKET studies!

13b Trial pathways / *Cervical cancer*

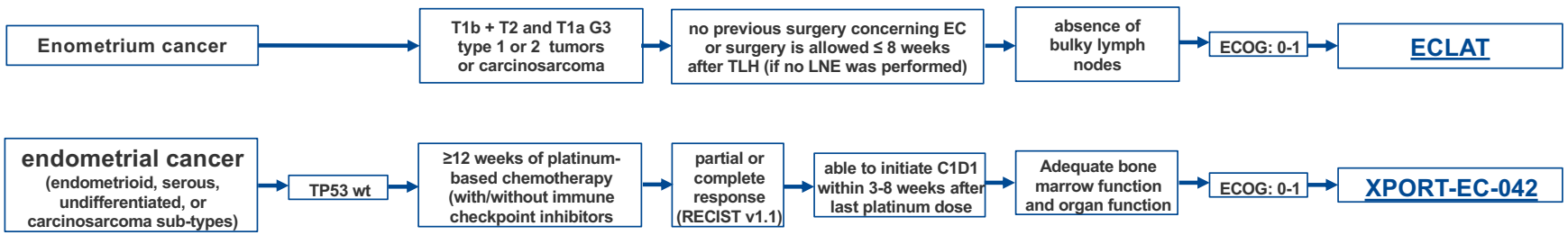


continue...

Please also check the possibility of inclusion in the BASKET studies!

Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

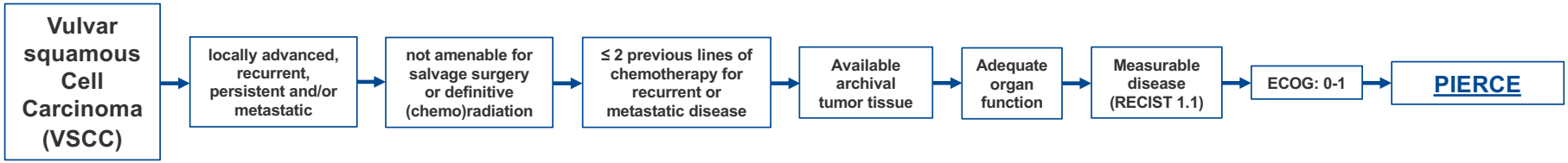
13c Trial pathways / *Endometrial cancer*



continue...

Please also check the possibility of inclusion in the BASKET studies!

13d Trial pathways / *Vulva cancer*



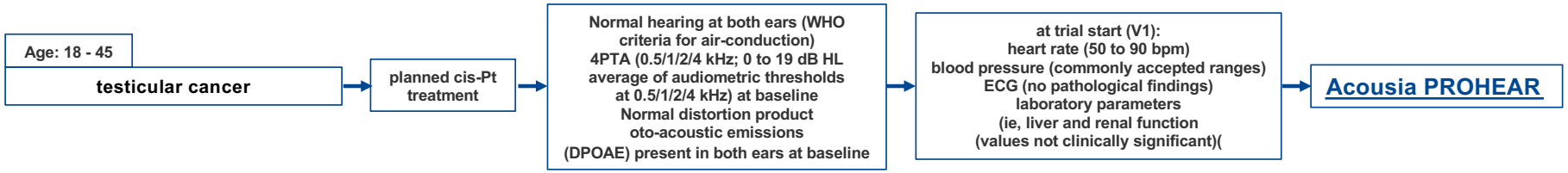
Please also check the possibility of inclusion in the BASKET studies!

Germ cell tumors

continue...

Contact at UCC Hamburg
PD Dr. med. Christoph Seidel, Tel.: 0152-2281 7710
Prof Dr. med. Carsten Bokemeyer, Tel.: 040 7410-52960

14 Trial pathways / *Germ cell tumors*



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Universitätsklinikum Hamburg-Eppendorf

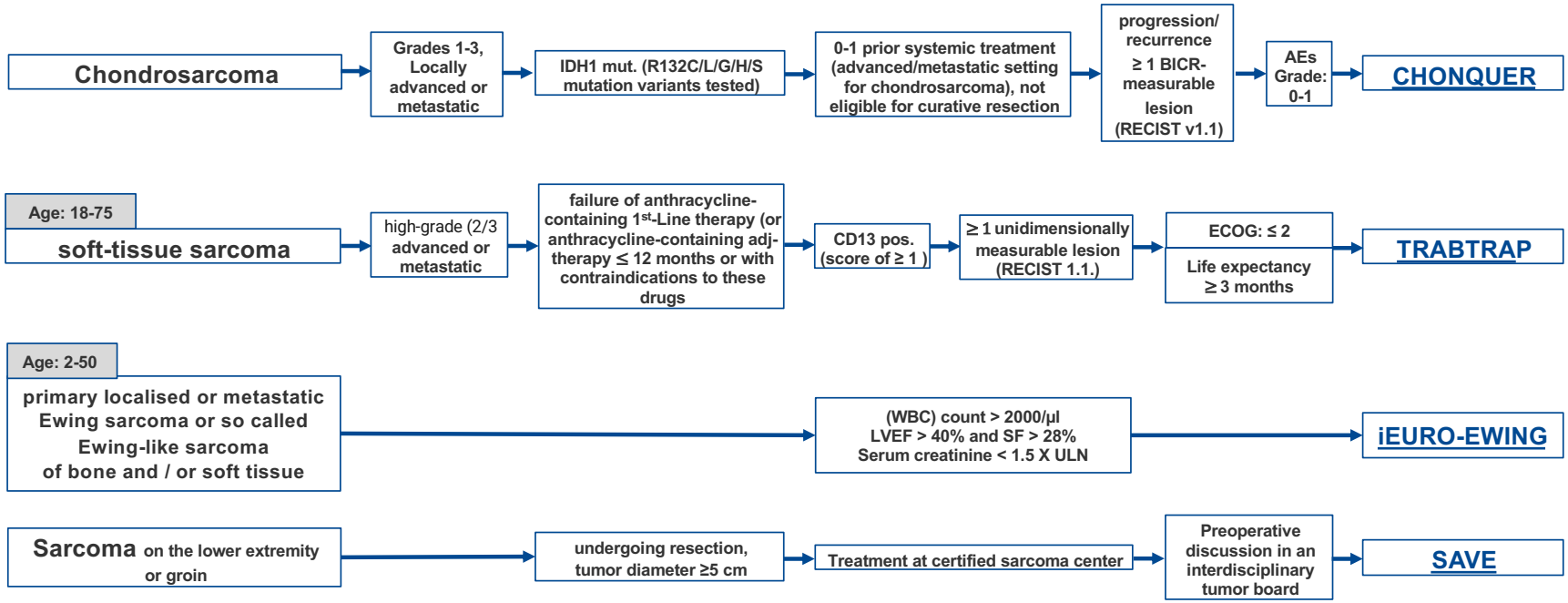
Please also check the possibility of inclusion in the BASKET studies!

Sarcomas

continue...

Contact at UCC Hamburg
Dr. med. Jana Käthe Striefler, Tel. 040/ 7410 53674

15 Trial pathways / *Sarcomas*



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Universitätsklinikum Hamburg-Eppendorf

Please also check the possibility of inclusion in the BASKET studies!

Hepatocellular cancer

16a resectable

16b unresectable

Contact at UCC Hamburg
PD Dr. med. Kornelius Schulze, Tel.: 0152-22817169

Trial pathways / *Hepatocellular cancer, resectable*

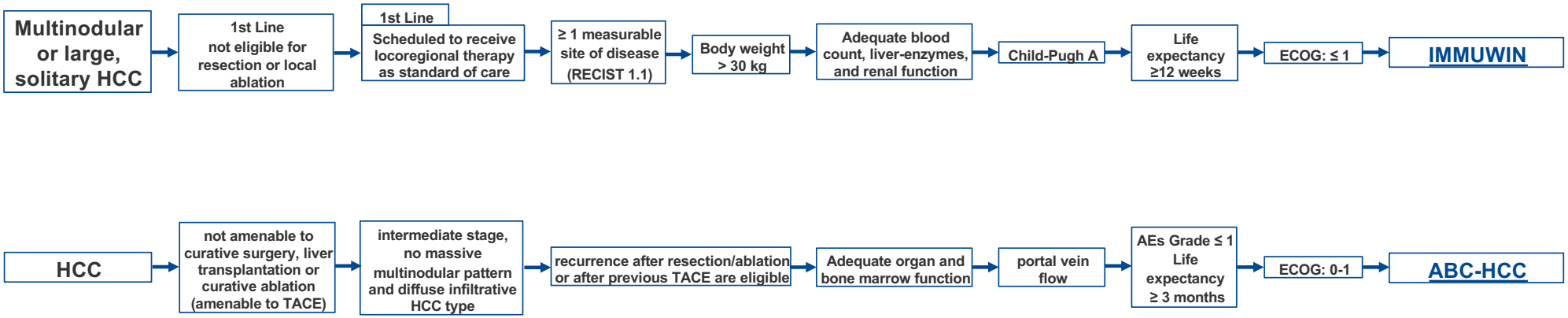
Entities

Currently no study options

continue...

Please also check the possibility of inclusion in the BASKET studies!

16b Trial pathways / *Hepatocellular cancer, unresectable*



Please also check the possibility of inclusion in the BASKET studies!

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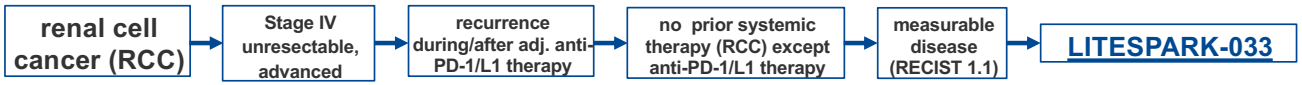
Universitätsklinikum Hamburg-Eppendorf

Renal cell cancer

continue...

Contact at UCC Hamburg
Prof. Dr. med. Gunhild von Amsberg, Tel.: 0152-22815585

17 Trial pathways / *Renal cell cancer*



Please also check the possibility of inclusion in the BASKET studies!

Skin tumors

18a ***Melanoma***

18b ***Other Neoplasms Skin***

18c ***(Uveal Melanoma)***

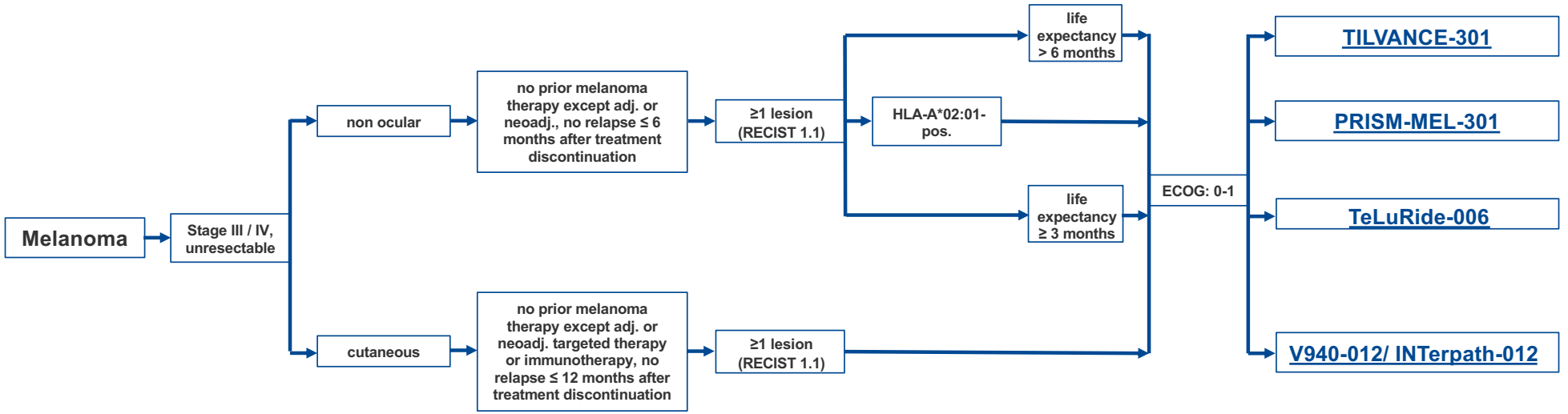
Contact at UCC Hamburg
Univ. Prof. Christoffer Gebhardt, Tel.: 040 7410-57626

18a Trial pathways / *Melanoma (neoadjuvant)*

continue...

Please also check the possibility of inclusion in the BASKET studies!

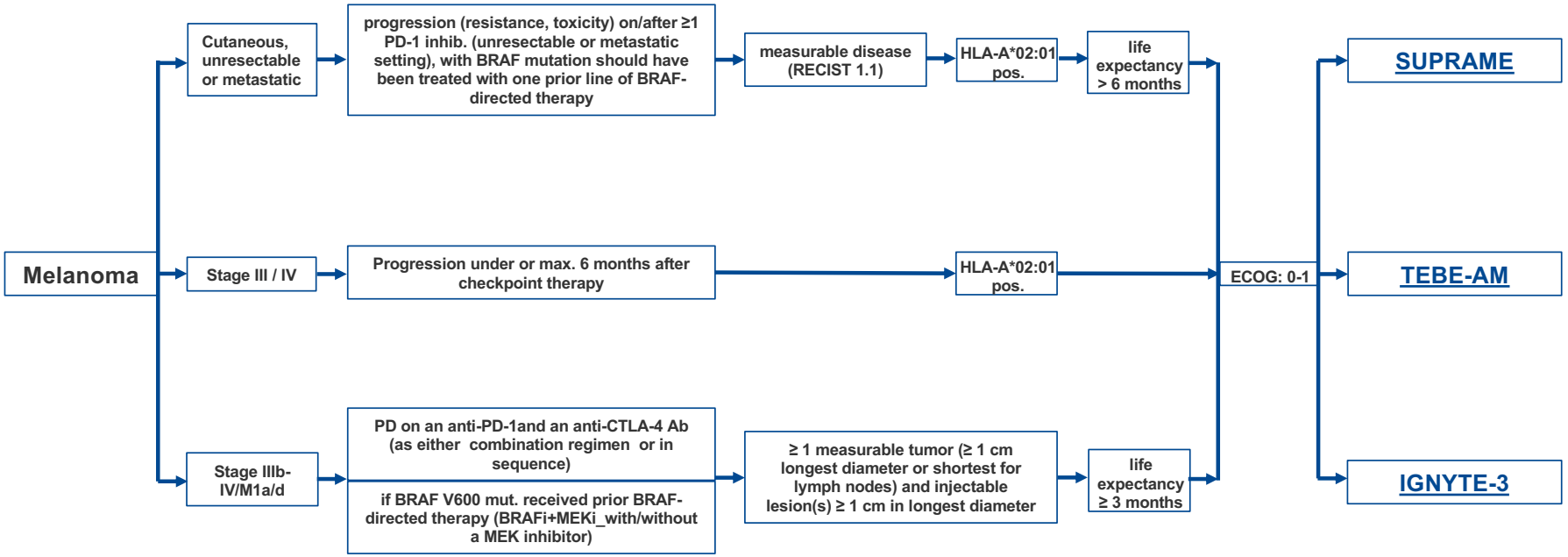
18a Trial pathways / *Melanoma (1st-Line)*



continue...

Please also check the possibility of inclusion in the BASKET studies!

18a Trial pathways / *Melanoma (2nd-Line)*



continue...

Please also check the possibility of inclusion in the BASKET studies!

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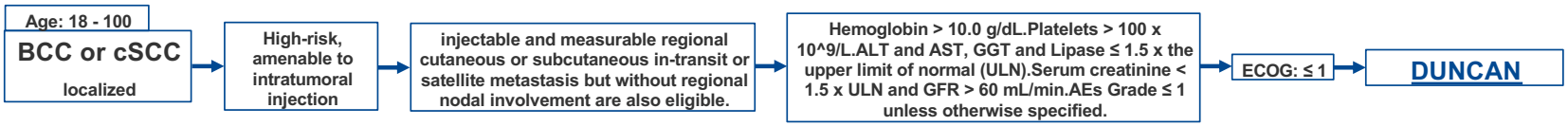
Universitätsklinikum Hamburg-Eppendorf

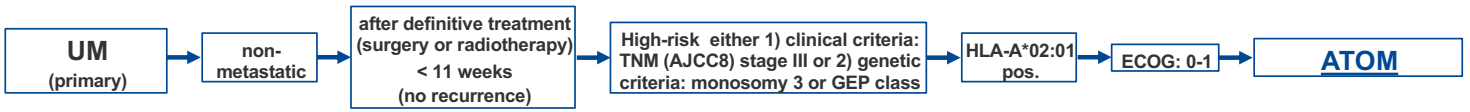
18b Trial pathways / *Other Neoplasms Skin*



continue...

Please also check the possibility of inclusion in the BASKET studies!

18c Trial pathways / *Uveal Melanoma (adjuvant)*



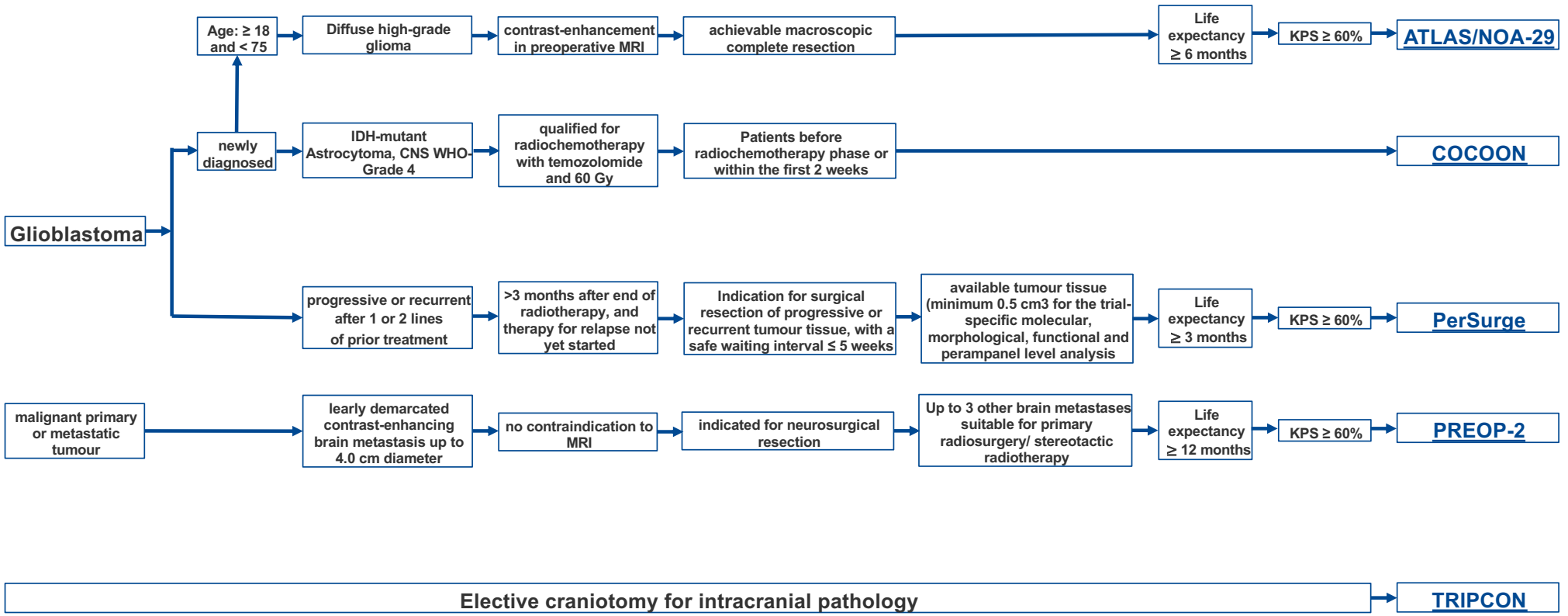
Please also check the possibility of inclusion in the BASKET studies!

Brain tumors

continue...

Contact at UCC Hamburg
Prof. Dr- med. Judith Dierlamm, Tel.: 040 7410-53782

19 Trial pathways / *Brain tumors*



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Universitätsklinikum Hamburg-Eppendorf

Please also check the possibility of inclusion in the BASKET studies!

GIST tumors

continue...

Contact at UCC Hamburg
Dr. med. Jana Käthe Striefler, Tel. 040/ 7410 53674

Currently no study options

Please also check the possibility of inclusion in the BASKET studies!

Side effects of oncological therapies

continue...

Contact at UCC Hamburg
PD Dr. med. Andreas Block, MBA, 040/ 7410-56305

22 Trial pathways / *Side effects of oncological therapies*

Please also check the possibility of inclusion in the BASKET studies!

Paediatric Oncology & Hematology

continue...

Contact at UCC Hamburg
Prof. Dr. med. Kai Witetchek, Tel. 040/ 7410 56822

GPO studies and register studies

http://www.kinderkrebsinfo.de/e1676/e9032/index_ger.html

Studienverbund Pädiatrische Hämatologie und Onkologie Nordwest – Gemeinsam für eine bessere Medizin. (studienverbund-nordwest.de)

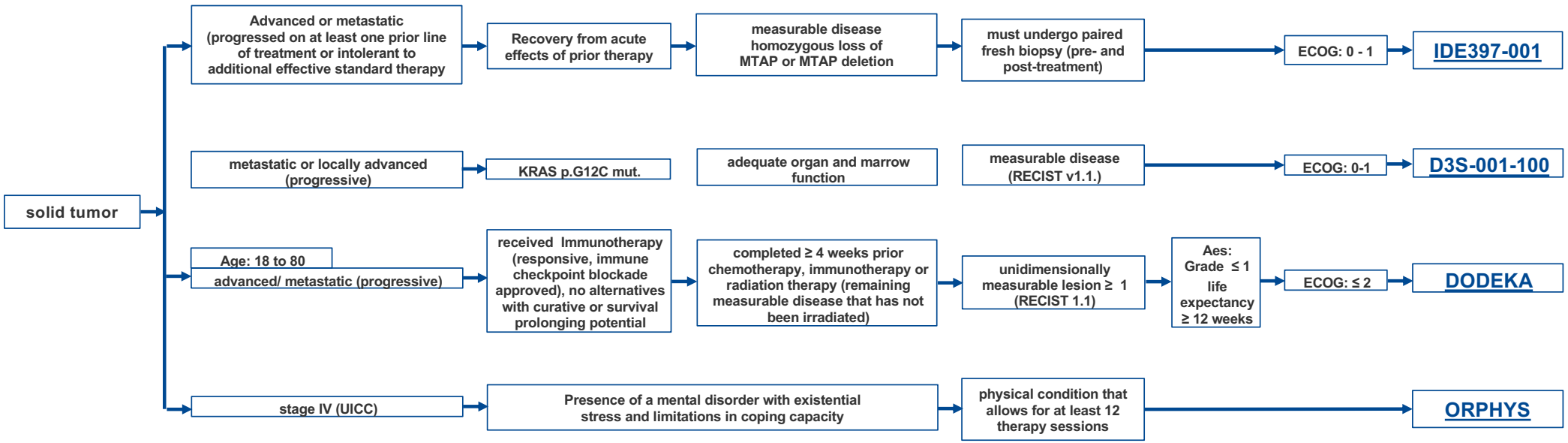
Please also check the possibility of inclusion in the BASKET studies!

Cross-entity studies „Basket studies“

continue...

Contact at UCC Hamburg
PD Dr. med. Andreas Block, MBA, 040/ 7410-56305
Dr. med. Winfried Alsdorf, 040 0152 22817664

23 Trial pathways / *Basket studies*



continue...

Please also check the possibility of inclusion in the BASKET studies!

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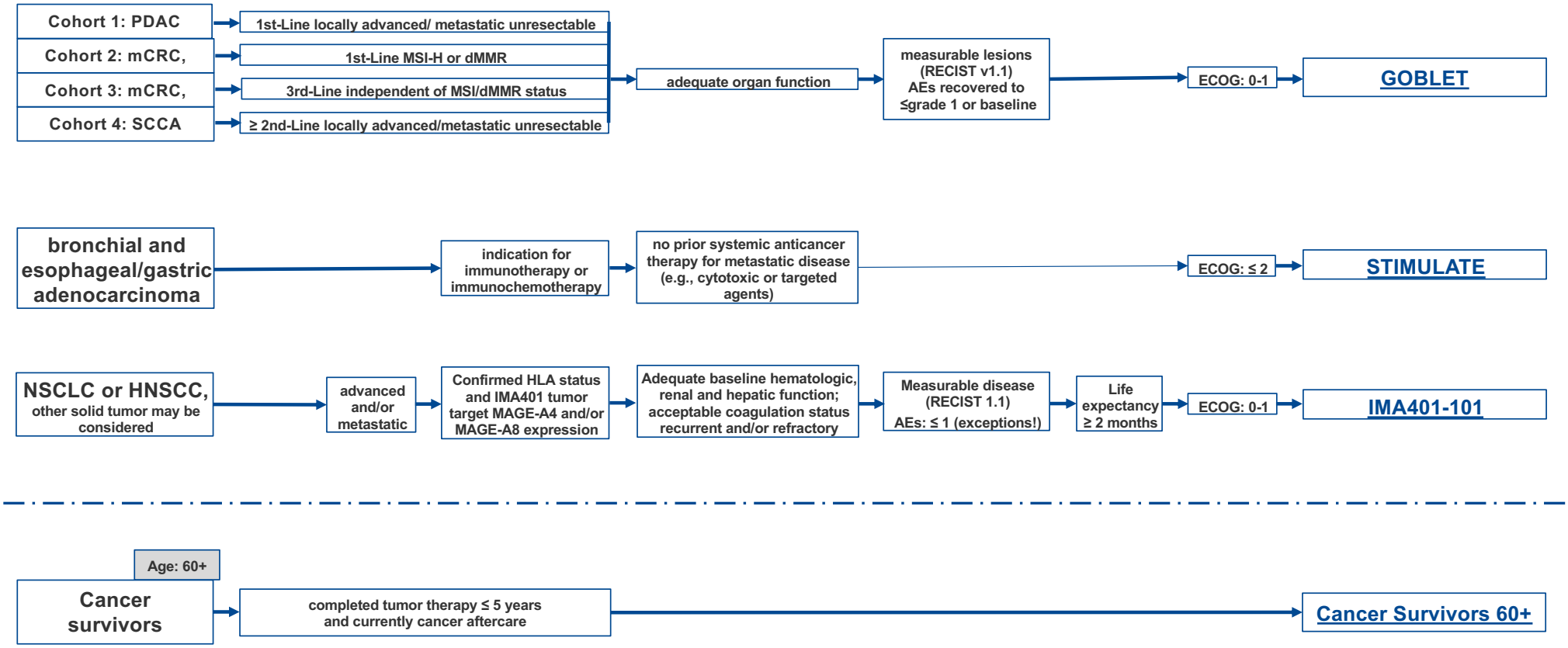
23 Trial pathways / *Basket studies*



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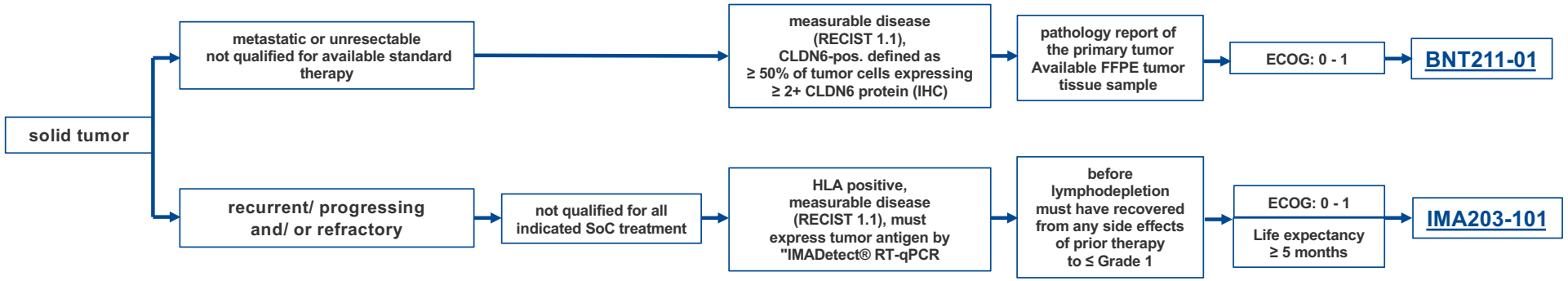
Please also check the possibility of inclusion in the BASKET studies!

Cellular Therapies

continue...

24 Trial pathways / *Cellular Therapies*



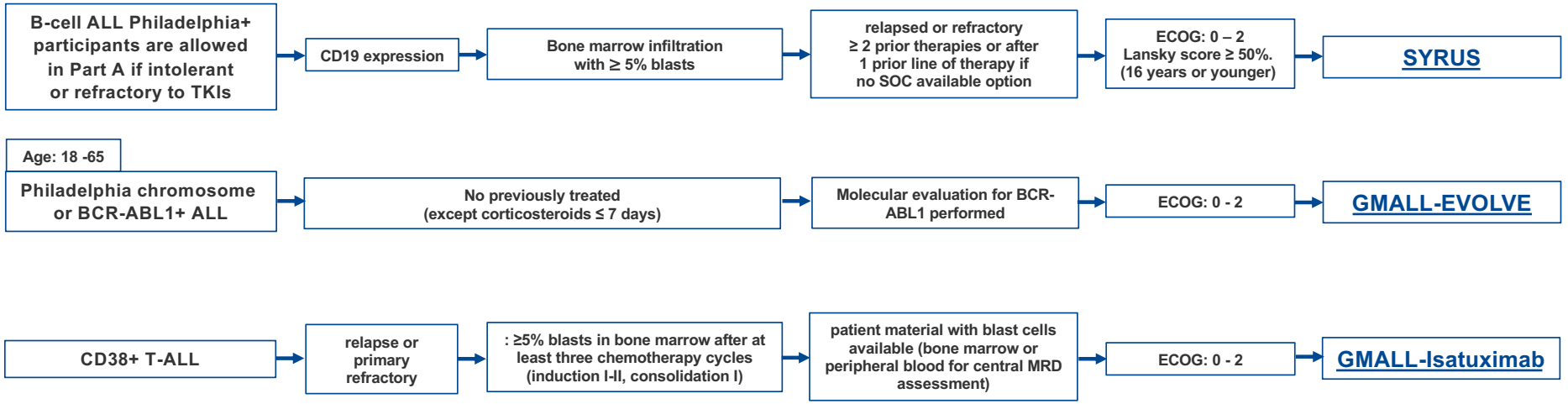
Please also check the possibility of inclusion in the BASKET studies!

Leukemias

- 25a ALL
- 25b AML/MDS
- 25c CLL
- 25d CML
- 25e aGVHD

Contact at UCC Hamburg
PD Dr. med. Franziska Westendorf , Tel. 0152 228 227 89 (ALL & AML)
Dr. med. Philippe Schafhausen, Tel: 040 7410-57122 (MDS & CML)
Dr. med. Minna Voigtländer, Tel. 0152 228 179 11 (CLL)

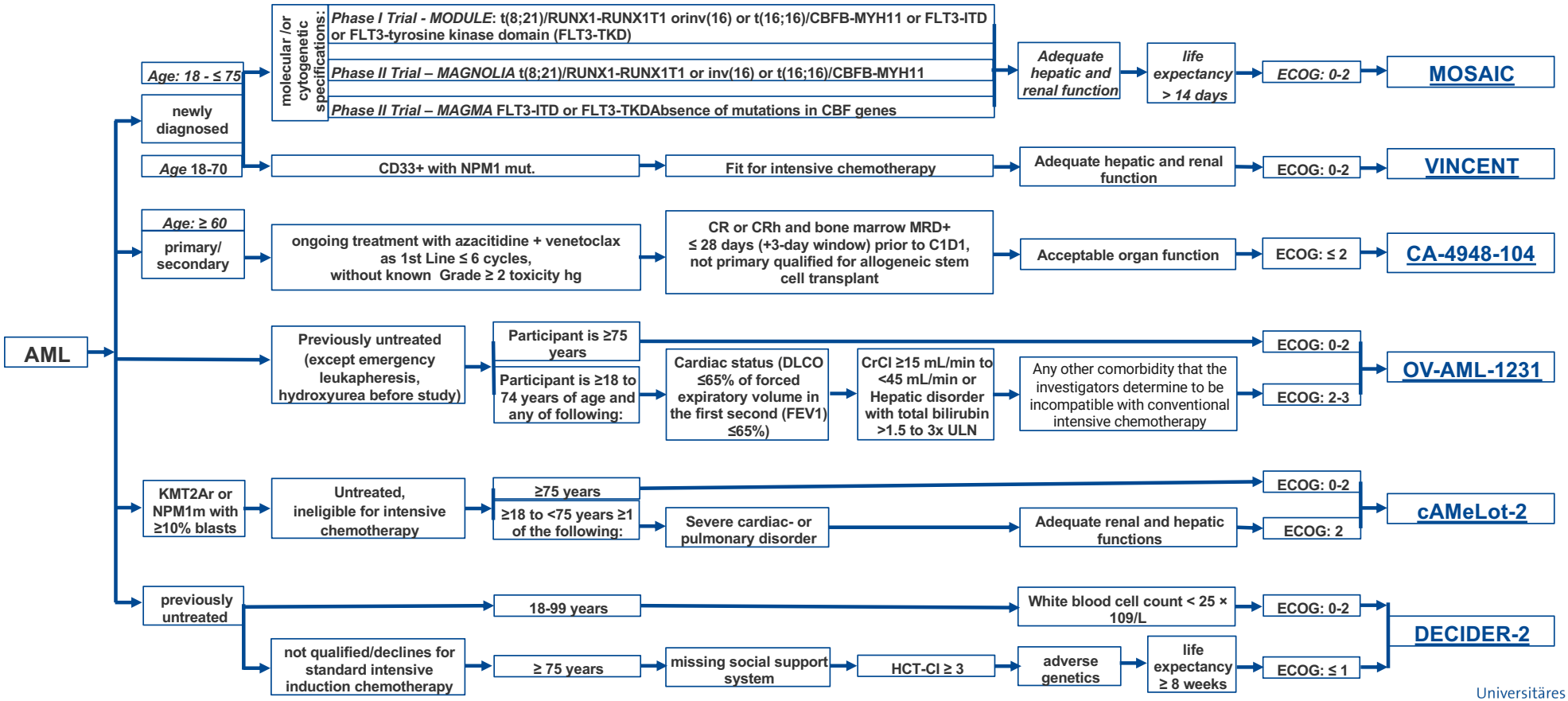
25a Trial pathways / *ALL*



continue...

Please also check the possibility of inclusion in the BASKET studies!

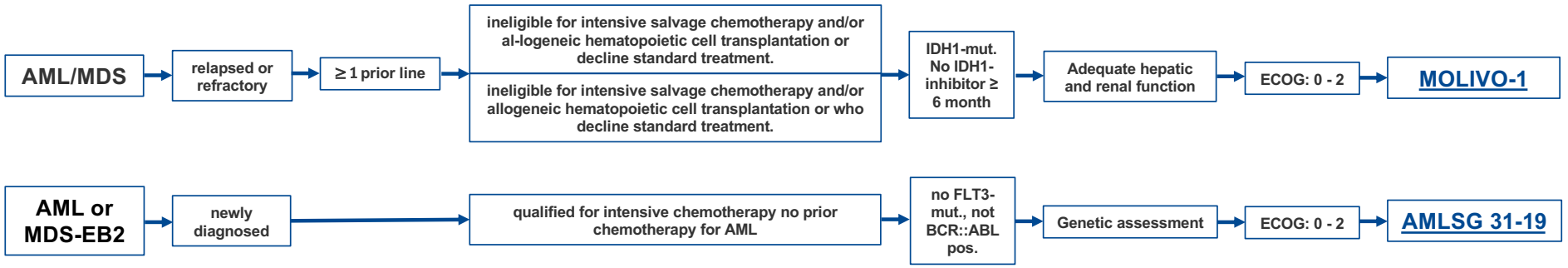
25b Trial pathways / *AML*



continue...

Please also check the possibility of inclusion in the BASKET studies!

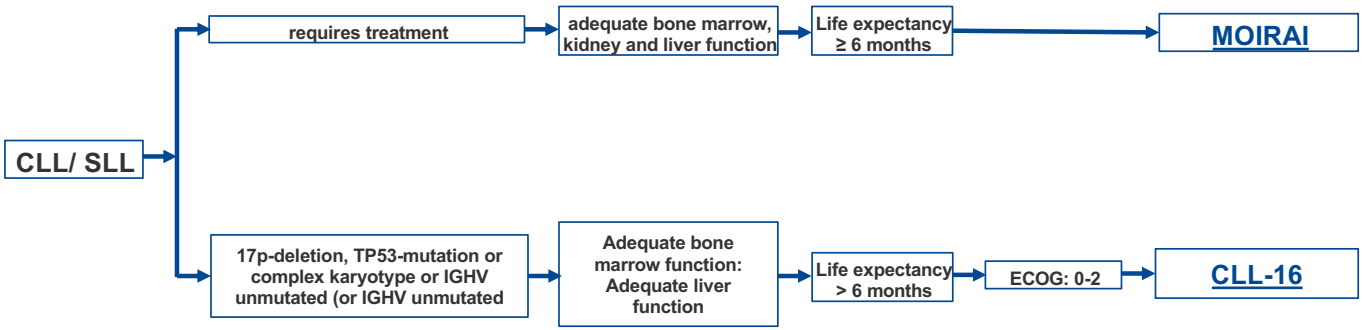
25b Trial pathways / *AML+MDS*



continue...

Please also check the possibility of inclusion in the BASKET studies!

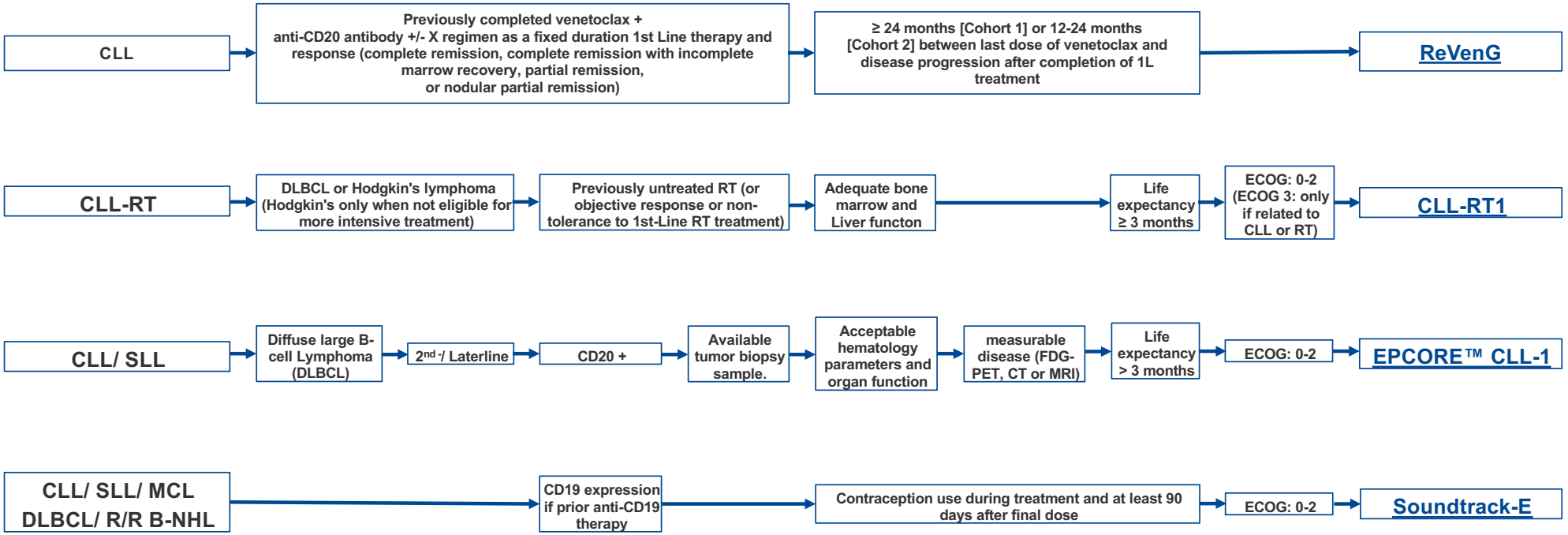
25c Trial pathways / *CLL* (Treatment naive CLL/SLL requires therapy)



continue...

Please also check the possibility of inclusion in the BASKET studies!

25c Trial pathways / *CLL (2nd-/laterline)*



continue...

Please also check the possibility of inclusion in the BASKET studies!

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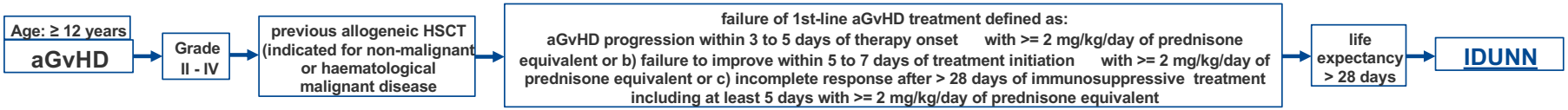
Universitätsklinikum Hamburg-Eppendorf

Currently no study options

continue...

Please also check the possibility of inclusion in the BASKET studies!

25d Trial pathways / *aGVHD*



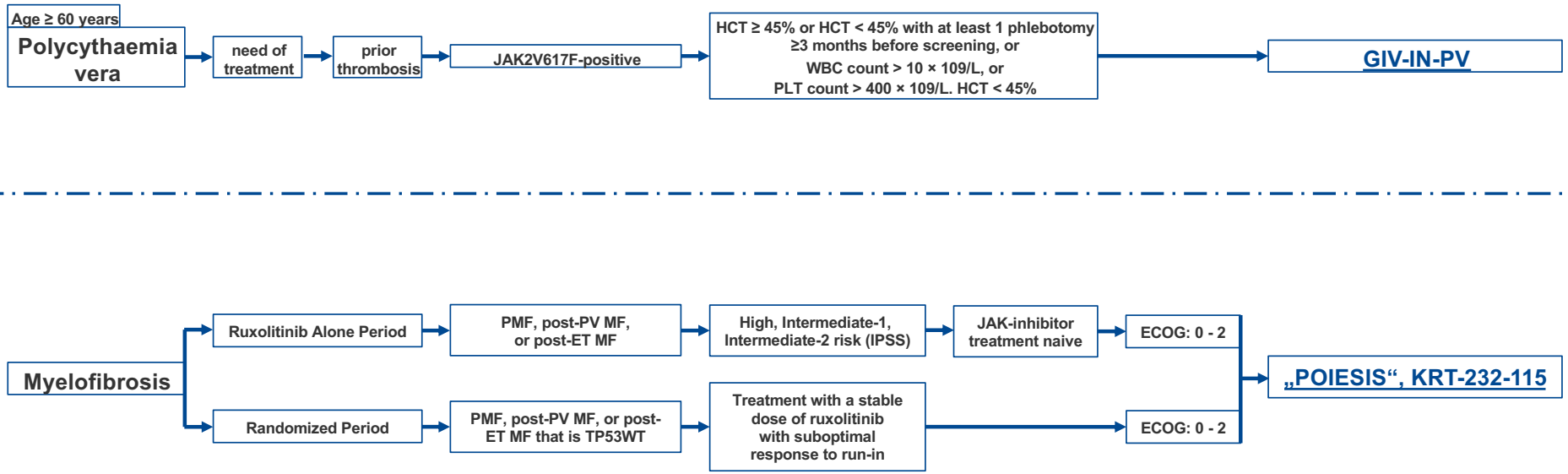
Please also check the possibility of inclusion in the BASKET studies!

Myeloproliferative neoplasms (MPN)

continue...

Contact at UCC Hamburg
Dr. med. Philippe Schafhausen, Tel: 040 7410-57122

26 Trial pathways / *MPN*



Please also check the possibility of inclusion in the BASKET studies!

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Universitätsklinikum Hamburg-Eppendorf

Mastocytosis

continue...

Contact at UCC Hamburg
Dr. med. Philippe Schafhausen, Tel: 040 7410-57122

Currently no study options

Please also check the possibility of inclusion in the BASKET studies!

Hodgkin's disease

continue...

Contact at UCC Hamburg
Prof. Dr- med. Judith Dierlamm, Tel.: 040 7410-53782

Currently no study options

Please also check the possibility of inclusion in the BASKET studies!

Non-Hodgkin's lymphoma (NHL) & Waldenström's disease

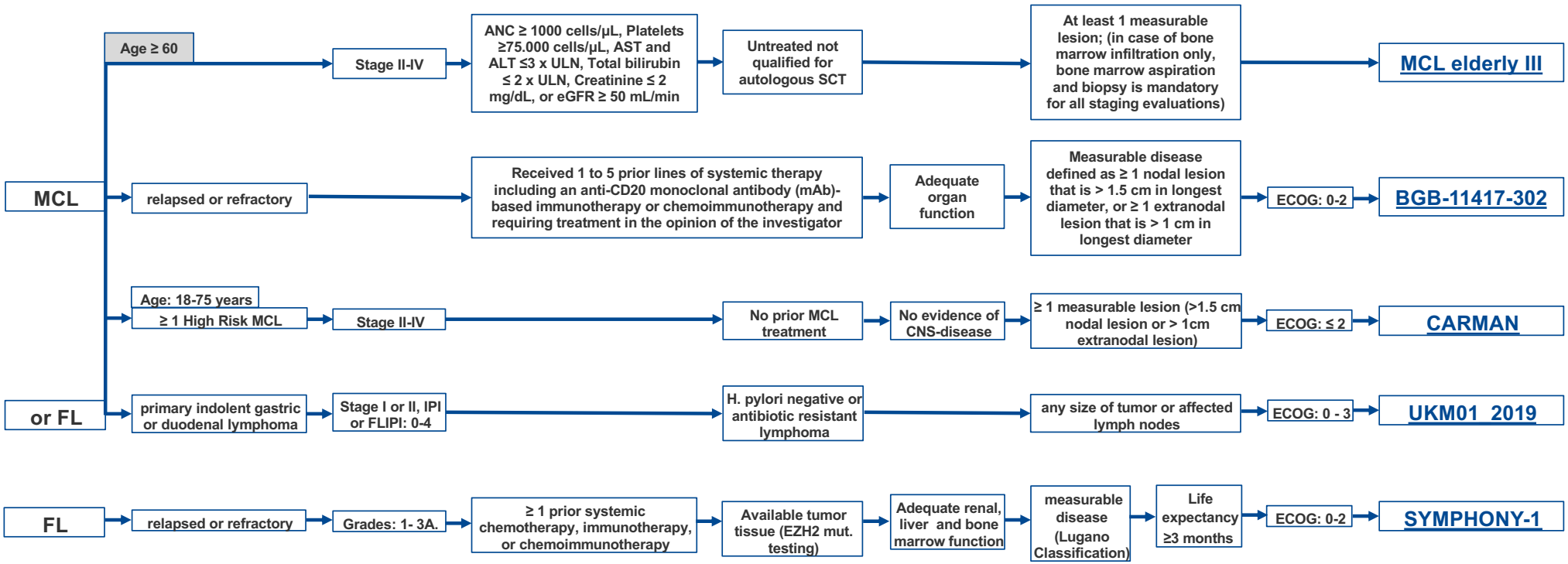
29a

29b

continue...

Contact at UCC Hamburg
Prof. Dr- med. Judith Dierlamm, Tel.: 040 7410-53782

29a Trial pathways / *NHL*



continue...

Please also check the possibility of inclusion in the BASKET studies!

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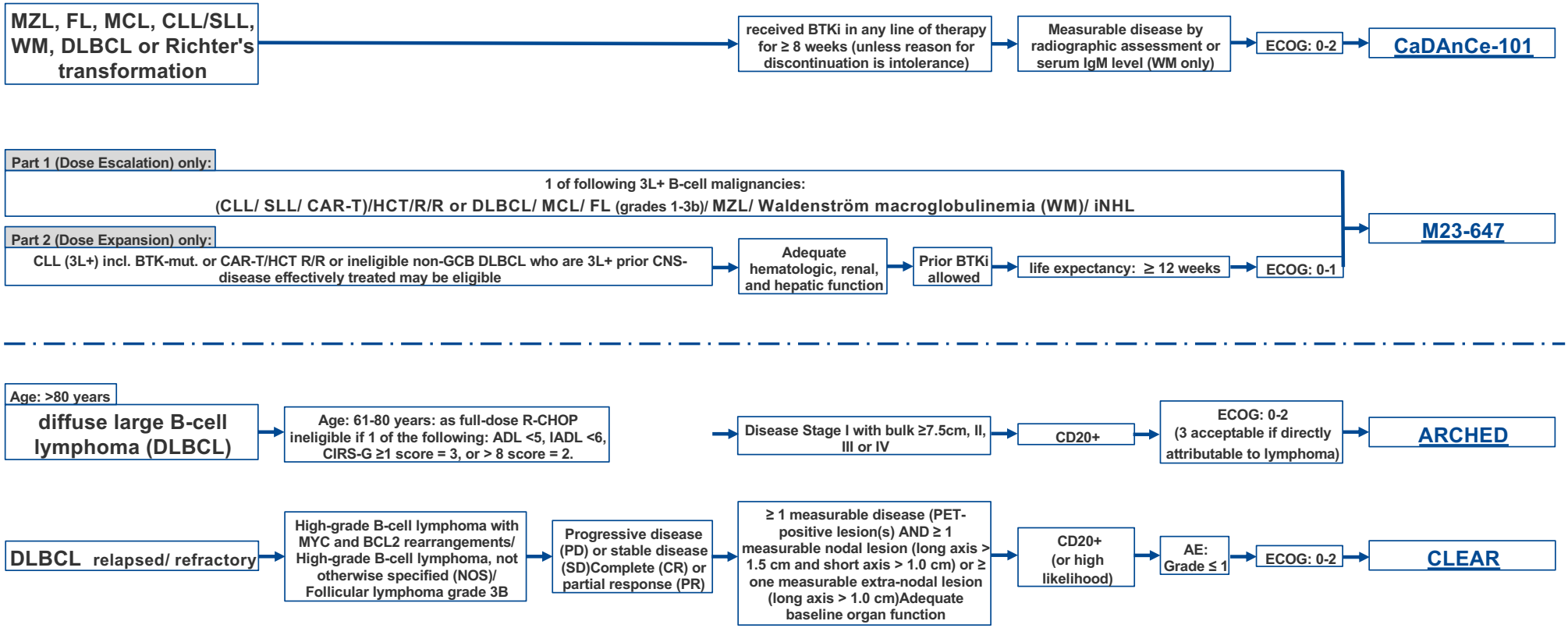
Universitätsklinikum Hamburg-Eppendorf

29a Trial pathways / *NHL*



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Universitätsklinikum Hamburg-Eppendorf

continue...

Please also check the possibility of inclusion in the BASKET studies!

Currently no study options

Please also check the possibility of inclusion in the BASKET studies!

Multiple Myeloma

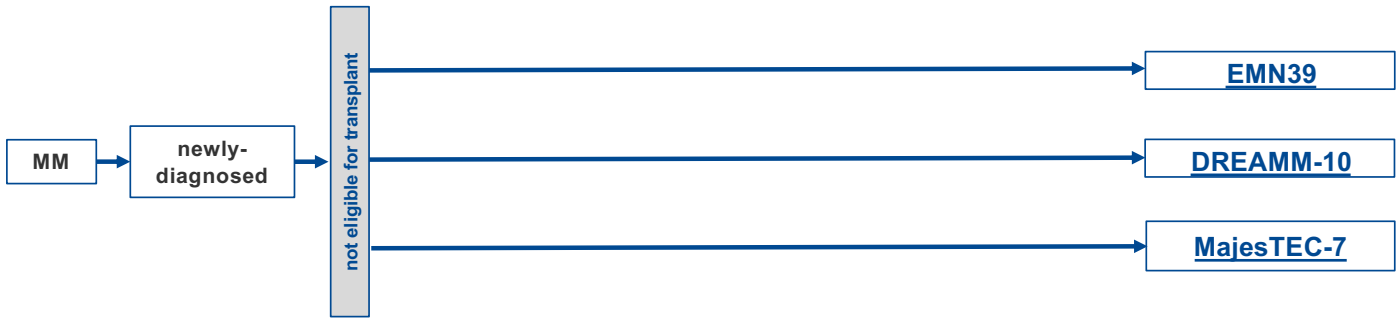
30a MM

30b r/r

30c r/r, t(11;14)

Contact at UCC Hamburg
Prof. Dr. med. Katja Weisel, Tel.: 040 7410-58787

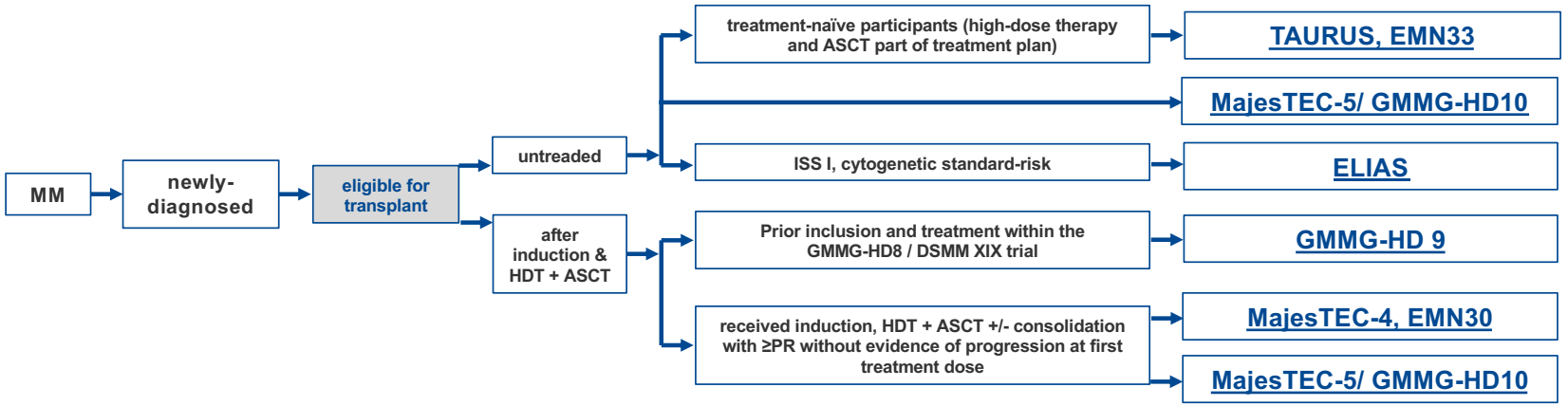
30a Trial pathways / *Multiple Myeloma*



continue...

Please also check the possibility of inclusion in the BASKET studies!

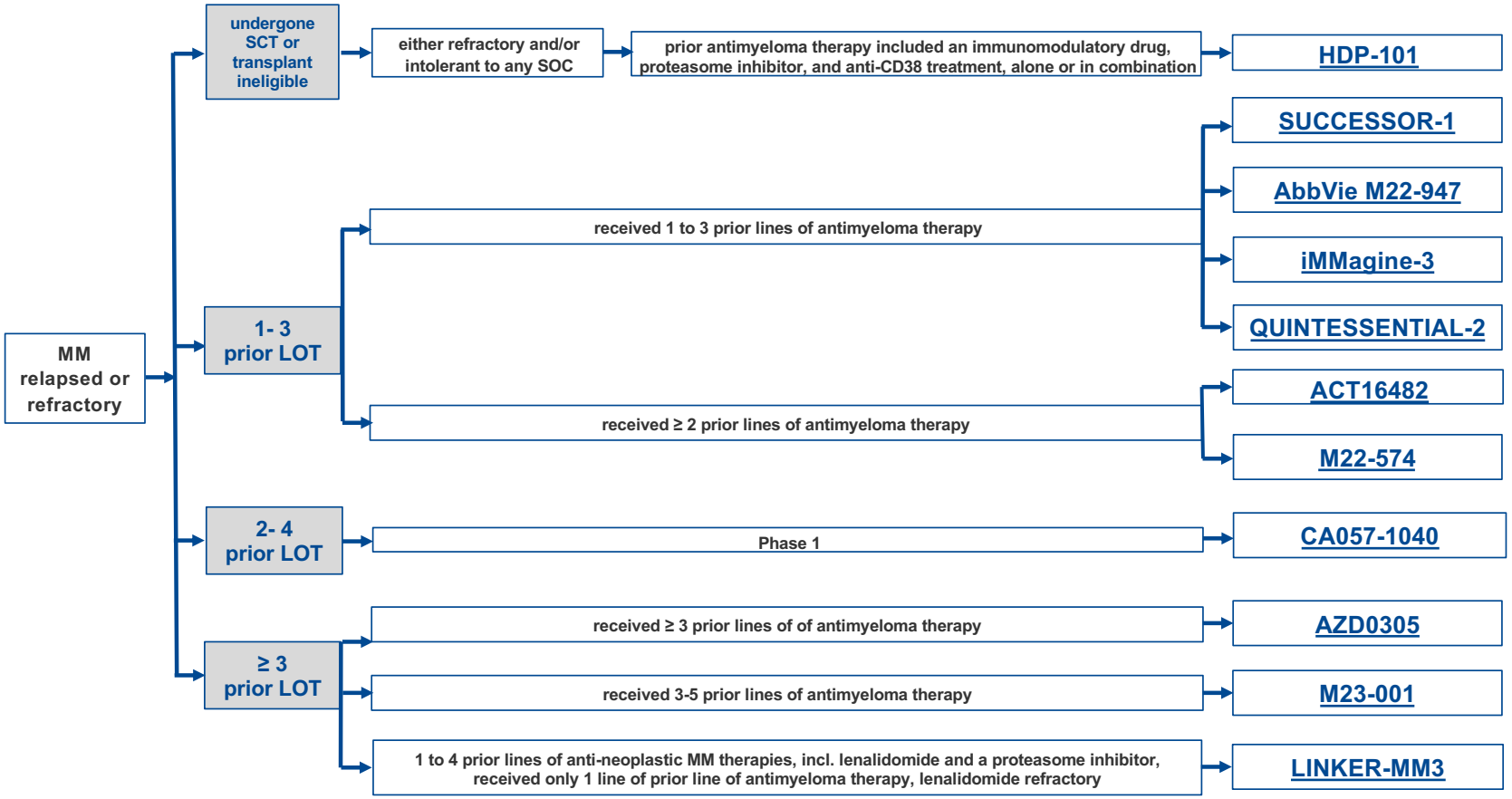
30a Trial pathways / *Multiple Myeloma*



continue...

Please also check the possibility of inclusion in the BASKET studies!

30b Trial pathways / *Multiple Myeloma_relapsed or refractory*



continue...

Please also check the possibility of inclusion in the BASKET studies!

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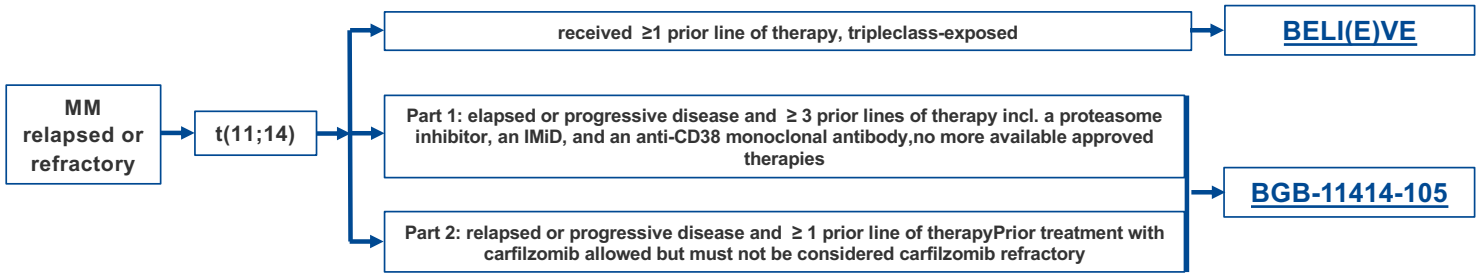
30b Trial pathways / *Multiple Myeloma_relapsed or refractory_ t(11;14)*



Please also check the possibility of inclusion in the BASKET studies!

Myelodysplastic syndrome (MDS)

continue...

Contact at UCC Hamburg
Dr. med. Philippe Schafhausen, Tel.: 040-7410-57122

31 Trial pathways / *MDS*

Currently no study options

Please also check the possibility of inclusion in the BASKET studies!

Anemia

continue...

Contact at UCC Hamburg
Dr. med. Philippe Schafhausen, Tel.: 040-7410-57122

Currently no study options

continue...

Please also check the possibility of inclusion in the BASKET studies!

Immune thrombocytopenia (ITP)

continue...

Contact at UCC Hamburg
Dr. med. Philippe Schafhausen, Tel.: 040-7410-57122

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Universitätsklinikum Hamburg-Eppendorf

Currently no study options

Please also check the possibility of inclusion in the BASKET studies!

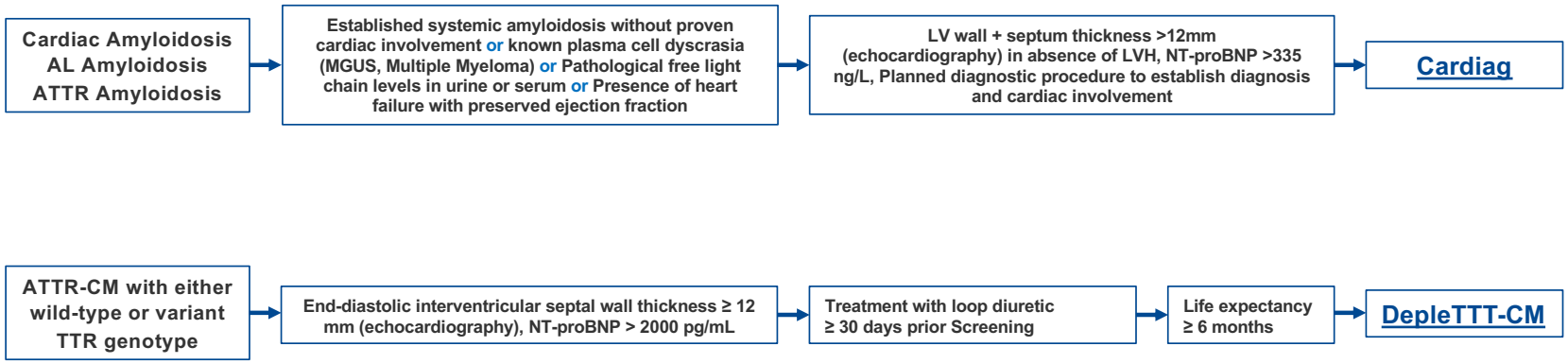
Amyloidosis

continue...

Contact at UCC Hamburg
Dr. med. Philippe Schafhausen, Tel.: 040-7410-57122

Trial pathways / *Amyloidosis*

Entities



Please also check the possibility of inclusion in the BASKET studies!

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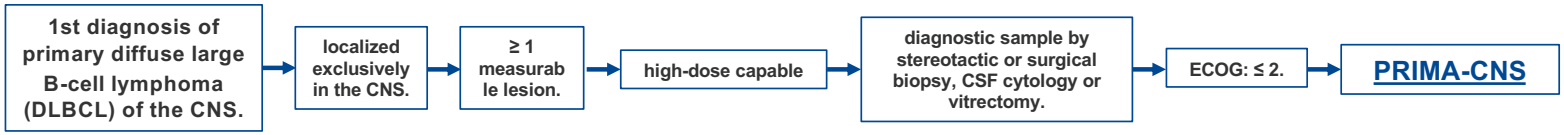
Universitätsklinikum Hamburg-Eppendorf

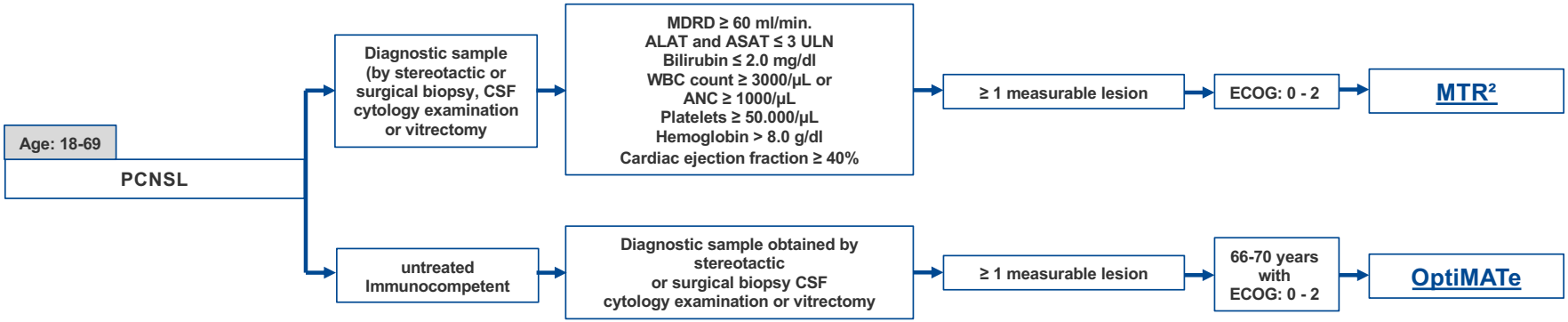
Primary CNS lymphomas (PCNSL)

continue...

Contact at UCC Hamburg
PD Dr. med. Minna Voigtländer, Tel.: 0152-22817911

35 Trial pathways / *PCNSL*





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Universitätsklinikum Hamburg-Eppendorf

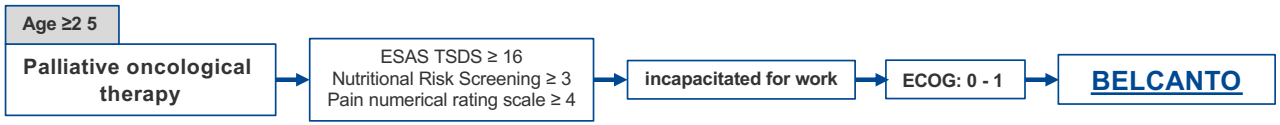
Please also check the possibility of inclusion in the BASKET studies!

Palliative studies

continue...

Contact at UCC Hamburg
Prof. Dr. med. Karin Oechsle, Tel.: 040 7410-50667

36 Trial pathways / *Palliative studies*



Please also check the possibility of inclusion in the BASKET studies!

Bronchial-Ca / Lung

continue...

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1 **„DeLLphi-301“**

A Phase 2 Study Evaluating the Efficacy, Safety, Tolerability, and Pharmacokinetics of AMG 757 in Subjects With Relapsed/Refractory Small Cell Lung cancer After Two or More Prior Lines of Treatment. The main aim of this study is to: -evaluate safety and efficacy (per Response Evaluation Criteria in Solid Tumors version 1.1 [RECIST 1.1] by investigator) of 2 dose levels of Tarlatamab for Part 1 only - evaluate anti-tumor activity of Tarlatamab as determined by objective response rate (ORR) per RECIST 1.1 by blinded independent central review (BICR) for Part 1 and 2

Condition: Relapsed/Refractory Small Cell Lung cancer

Primary Completion Date: 2025-10-31

Phase: II

Intervention / Treatment: DRUG: **Tarlatamab**

Inclusion Criteria:

Participant has provided informed consent/assent prior to initiation of any study specific activities/procedures. / Male and female participants ≥ 18 years of age (or legal adult age within country) at the time of signing the informed consent. / Histologically or cytologically confirmed relapsed/refractory SCLC Participants who progressed or recurred following 1 platinum-based regimen and at least 1 other prior line of therapy. / Participants willing to provide archived tumor tissue samples or willing to undergo pretreatment tumor biopsy. / Eastern Cooperative Oncology Group (ECOG) performance status of 0 1. / Minimum life expectancy of 12 weeks. Measurable lesions as defined per RECIST 1.1 within 21 days prior to the first dose of tarlatamab. Participants with treated brain metastases are eligible provided they meet defined criteria.

see Link:

clinicaltrials.gov/NCT06211036

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG

Universitätsklinikum Hamburg-Eppendorf

1 „ARTEMIDE-Lung03“

A randomized, double-blind, multicenter, global phase III study of rilvegostomig or pembrolizumab in combination with platinum-based chemotherapy for the first-line treatment of patients with metastatic non-squamous non-small cell lung cancer whose tumors express PD-L1

Condition: Non-squamous Non-small Cell Lung cancer

Primary Completion Date: 2029-05-10

Phase: III

Intervention / Treatment: DRUG: **Rilvegostomig/ Pembrolizumab/ Carboplatin/ Cisplatin/ Pemetrexed**

Inclusion Criteria:

Histologically or cytologically documented non-squamous NSCLC. / Stage IV mNSCLC (based on the American Joint Committee on Cancer Edition 8) not amenable to curative treatment.+ / Absence of sensitizing EGFR mutations (including, but not limited to, exon 19 deletion and exon 21 L858R, exon 21 L861Q, exon 18 G719X, and exon 20 S768I mutations) and ALK and ROS1 rearrangements. / Absence of documented tumor genomic mutation results from tests conducted as part of standard local practice in any other actionable driver oncogenes for which there are locally approved targeted 1L therapies. / Provision of acceptable tumor sample, to confirm tumor PD-L1 expression TC ≥ 1%. / At least one lesion not previously irradiated that qualifies as a RECIST 1.1 TL at baseline and can be accurately measured at baseline as ≥ 10 mm in the longest diameter (except lymph nodes, which must have short axis ≥ 15 mm) with CT or MRI and is suitable for accurate repeated measurements. / Adequate organ and bone marrow function

Exclusion Criteria:

Presence of small cell and neuroendocrine histology components. / Brain metastases unless asymptomatic, stable, and not requiring steroids or anticonvulsants for at least 7 days prior to randomization. A minimum of 2 weeks must have elapsed between the end of local therapy (brain radiotherapy or surgery) and randomization. Participants must have recovered from the acute toxic effect of radiotherapy (eg, dizziness and signs of increased intracranial pressure) or surgery prior to randomization. / Any prior systemic therapy received for advanced or mNSCLC. Prior systemic therapy in the neoadjuvant or adjuvant setting and/or definitive radio- or chemoradiotherapy for early-stage disease are allowed, provided that recurrence or progression has occurred > 12 months after the end of treatment. / Any prior exposure to an anti-TIGIT therapy or any other anticancer therapy targeting immune-regulatory receptors or mechanisms. / Any prior treatment with an anti-PD-1 or anti-PD-L1 agent. / History of another primary malignancy except for malignancy treated with curative intent with no known active disease ≥ 2 years before the first dose of study intervention and of low potential risk for recurrence. / Active or prior documented autoimmune or inflammatory disorders requiring chronic treatment with steroids or other immunosuppressive treatment. / Active primary immunodeficiency/active infectious disease(s). / Active tuberculosis infection.

see Link:

clinicaltrials.gov/NCT06627647

Study Test Center	PI / SC	Phone	E-Mail
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1 „TroFuse-007“, MK-2870-007

A randomized, open-label phase 3 study of MK-2870 in combination with pembrolizumab versus pembrolizumab monotherapy in the first-line treatment of participants with metastatic non-small cell lung cancer with PD-L1 TPS greater than or equal to 50%

Condition: Non-small Cell Lung cancer

Primary Completion Date: N/A

Phase: III

Intervention / Treatment: BIOLOGICAL**: Sacituzumab tirumotecan/ Pembrolizumab**

Inclusion Criteria:

Histologically or cytologically confirmed diagnosis of squamous or nonsquamous NSCLC / Confirmation that epidermal growth factor receptor- (EGFR-), anaplastic lymphoma kinase- (ALK-), or proto-oncogene tyrosine-protein kinase ROS (ROS1-) directed therapy is not indicated as primary therapy / Provided tumor tissue that demonstrates programmed cell death ligand 1 (PD-L1) expression in ≥50% of tumor cells as assessed by an immunohistochemistry (IHC) central laboratory / An Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1 assessed within 7 days before randomization. / A life expectancy of at least 3 months. / Human immunodeficiency virus (HIV)-infected participants must have well controlled HIV on antiretroviral therapy (ART)

Exclusion Criteria:

Diagnosis of small cell lung cancer or, for mixed tumors, presence of small cell elements. / Has Grade ≥2 peripheral neuropathy. / History of documented severe dry eye syndrome, severe Meibomian gland disease and/or blepharitis, or corneal disease that prevents/delays corneal healing. / Has active inflammatory bowel disease requiring immunosuppressive medication or previous clear history of inflammatory bowel disease (eg, Crohn's disease, ulcerative colitis, or chronic diarrhea). / Has uncontrolled, significant cardiovascular disease or cerebrovascular disease within the 6 months preceding study intervention. / Received prior systemic anticancer therapy for their metastatic NSCLC. / Received prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent, or with an agent directed to another stimulatory or coinhibitory T-cell receptor Note: Prior treatment with an anti-PD-1, anti-PD- L1, or anti-PD-L2 agent in the neoadjuvant or adjuvant setting for nonmetastatic resectable NSCLC is allowed as long as therapy was completed at least 12 months before diagnosis of metastatic NSCLC. / Received prior systemic anticancer therapy including investigational agents within 4 weeks before randomization. Received radiation therapy to the lung that is >30 Gy within 6 months of start of study intervention. / Received prior radiotherapy within 2 weeks of start of study intervention, or radiation-related toxicities, requiring corticosteroids. / Received a live or live-attenuated vaccine within 30 days before the first dose of study intervention. Administration of killed vaccines are allowed. / Diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy / Known additional malignancy that is progressing or has required active treatment within the past 3 years. / Known active central nervous system (CNS) metastases and/or carcinomatous meningitis. / Known intolerance to sacituzumab tirumotecan or pembrolizumab and/or any of their excipients; for pembrolizumab, severe hypersensitivity (≥Grade 3) is exclusionary. / Known hypersensitivity to sacituzumab tirumotecan or other biologic therapy. / Active autoimmune disease that has required systemic treatment in the past 2 years. / History of (noninfectious) pneumonitis/interstitial lung disease (ILD) that required steroids or has current pneumonitis/ILD. / Active infection requiring systemic therapy / Concurrent active Hepatitis B and Hepatitis C virus infection. / Human immunodeficiency virus (HIV)-infected participants with a history of Kaposi's sarcoma and/or Multicentric Castleman's Disease. / History of allogeneic tissue/solid organ transplant. / Requires treatment with a strong inhibitor or inducer of Cytochrome P450 3A4 (CYP3A4) at least 14 days before the first dose of study intervention and throughout the study.

see Link:

clinicaltrials.gov/NCT06170788

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Universitäres Cancer Center HAMBURG

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1 „Krascendo 1“, BO45217

A randomized, open-label, multicenter, phase III study to evaluate the efficacy and safety of divarasib versus sotorasib or adagrasib in patients with previously treated KRAS G12C-positive advanced or metastatic non-small cell lung cancer

Condition: Non-small Cell Lung cancer, KRAS G12C Lung Cancer

Primary Completion Date: 2026-09-23

Phase: III
Intervention / Treatment: DRUG: **Divarasib/ Sotorasib/ Adagrasib**

Inclusion Criteria:
Unequivocal histologically or cytologically confirmed diagnosis of metastatic or locally advanced NSCLC not amenable to treatment with surgical resection or combined chemoradiation / Disease progression during or after treatment with at least one prior systemic therapy but no more than three lines of prior systemic therapy in the advanced or metastatic setting / Measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 / Documentation of the presence of a KRAS G12C mutation / Availability of a representative formalin-fixed, paraffin-embedded (FFPE) tumor specimen in a paraffin block (preferred) or 10-15 (15 preferred) unstained, freshly cut, serial slides with an associated pathology report / Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 / Life expectancy of >= 12 weeks

Exclusion Criteria:
Known hypersensitivity to any of the components of divarasib, or sotorasib or adagrasib / Malabsorption syndrome or other condition that would interfere with enteral absorption / Known concomitant second oncogenic driver / Mixed small-cell lung cancer or large cell neuroendocrine histology / Known and untreated, or active central nervous system (CNS) metastases / Leptomeningeal disease or carcinomatous meningitis / Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures biweekly or more frequently / Any infection that, in the opinion of the investigator, could impact patient safety, or treatment with therapeutic oral or IV antibiotics within 14 days prior to Day 1 of Cycle 1 / Prior treatment with any KRAS G12C inhibitor or pan-KRAS/RAS inhibitor / More than 30 Gy of radiotherapy to the lung within 6 months of randomization / Uncontrolled tumor-related pain / Unresolved toxicities from prior anticancer therapy / History of malignancy within 5 years prior to screening, with the exception of the cancer under investigation in this study and malignancies with a negligible risk of metastasis or death (e.g., 5-year OS rate >90%), such as adequately treated carcinoma in situ of the cervix, nonmelanoma skin carcinoma, localized prostate cancer, ductal carcinoma in situ, or Stage I uterine cancer
see Link:

clinicaltrials.gov/NCT06627647

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1 „R3767-ONC-2266“, Regeneron 2266

A phase 2 perioperative study of fianlimab and cemiplimab in combination with chemotherapy versus cemiplimab in combination with chemotherapy in patients with resectable early-stage NSCLC (stage II to IIIB [N2])

Condition: Resectable Non-small Cell Lung cancer

Primary Completion Date: 2025-09-28

Phase: II

Intervention / Treatment: DRUG**: Fianlimab/ Cemiplimab/ Pemetrexed/ Paclitaxel/ Carboplatin/ Cisplatin/ Placebo**

Inclusion Criteria:

Patients with newly diagnosed, histologically confirmed, fully resectable stage II to IIIB (N2) NSCLC as per American Joint Committee on Cancer (AJCC) version 8 / For patients with evidence of mediastinal adenopathy on imaging, mediastinal lymph node sampling is required as defined in the protocol / All patients must have disease status showing no evidence of distant metastases documented by a complete physical examination and imaging studies performed within 4 weeks prior to randomization as defined in the protocol / A patient must have an evaluable Programmed cell death ligand-1 (PD-L1) / Immunohistochemistry (IHC) result as defined in the protocol / Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 / Adequate bone marrow, hepatic and kidney function as defined in the protocol

Exclusion Criteria:

Any evidence of locally advanced unresectable or metastatic disease as defined in the protocol / Patients with tumors with known Epidermal growth factor receptor (EGFR) gene mutations, anaplastic lymphoma kinase (ALK) gene translocations as defined in the protocol / Uncontrolled infection with human immunodeficiency virus (HIV), hepatitis B (HBV) or hepatitis C virus (HCV) infection as defined in the protocol / Treatment with anti-cancer therapy including immunotherapy, chemotherapy, radiotherapy, or biological therapy in the 3 years prior to randomization. Adjuvant hormonotherapy used for breast cancer or other hormone-sensitive cancers in long term remission is allowed. / Patients with a history of myocarditis

see Link:

clinicaltrials.gov/NCT06161441

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1 „SUNRAY-01“,

A global pivotal study in participants with KRAS G12C-mutated, locally advanced or metastatic non-small cell lung cancer comparing initial treatment with LY3537982 and pembrolizumab versus placebo and pembrolizumab in patients with PD-L1 expression ≥50% or LY3537982 and pembrolizumab, pemetrexed, platinum versus placebo and pembrolizumab, pemetrexed, platinum regardless of PD-L1 expression

Condition: Carcinoma, Non-small Cell Lung, Neoplasm Metastasis

Primary Completion Date: 2026-10

Phase: III

Intervention / Treatment: DRUG**: LY3537982/ Pembrolizumab/ Placebo/ Cisplatin/ Carboplatin/ Pemetrexed**

Inclusion Criteria:

Histologically or cytologically confirmed NSCLC with Stage IIIB-IIIC or Stage IV disease, not suitable for curative intent radical surgery or radiation therapy. / Part B and Safety Lead-In Part B: the histology of the tumor must be predominantly non-squamous (in line with pemetrexed label). / Must have disease with evidence of KRAS G12C mutation. / Must have known programmed death-ligand 1 (PD-L1) expression **Part A:** Greater than or equal to (≥)50 percent (%). **Part B**: 0% to 100%. / Must have measurable disease per RECIST v1.1. / Must have an ECOG performance status of 0 or 1. / Estimated life expectancy ≥12 weeks. / Ability to swallow capsules. / Must have adequate laboratory parameters. / Contraceptive use should be consistent with local regulations for those participating in clinical studies. / **Women of childbearing potential** must Have a negative pregnancy test. / Not be breastfeeding during treatment

Exclusion Criteria:

Have a documented additional validated targetable oncogenic driver mutation or alteration in genes such as epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), BRAF (V600E), human epidermal growth factor receptor 2 (HER2), MET (exon 14), ROS1, rearranged during transfection (RET), or neurotrophic tyrosine receptor kinase (NTRK)1/2/3. / Have had any of the following prior to randomization: / -- Prior systemic therapy (chemotherapy, immunotherapy, targeted therapy, or biological therapy) for advanced or metastatic NSCLC. / --- 1 cycle of standard-of-care treatment prior to study enrollment will be allowed for cases where immediate treatment is clinically indicated: / Have known active central nervous system metastases and/or carcinomatous meningitis.

Exclusion Criteria for Participants receiving Pemetrexed and Platinum (Part B and Safety Lead-In Part B):

Have predominantly squamous cell histology for NSCLC / Is unable to interrupt aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs) / Is unable or unwilling to take folic acid or vitamin B12 supplementation.

see Link:

clinicaltrials.gov/NCT06119581

Study Test Center	PI / SC	Phone	E-Mail
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1 „TROPION-Lung10“,

A Phase III, Randomised, Open-label, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig or Rilvegostomig Monotherapy Versus Pembrolizumab Monotherapy for the First-line Treatment of Participants With Locally-advanced or Metastatic Non-squamous NSCLC With High PD-L1 Expression (TC ≥ 50%) and Without Actionable Genomic Alterations (TROPION-Lung10)

Condition: Non-Small Cell Lung Cancer

Primary Completion Date: 2028-04-24

Phase: III

Intervention / Treatment: DRUG**: Datopotamab Deruxtecan/ Rilvegostomig/ Pembrolizumab**

Inclusion Criteria:

Histologically or cytologically documented non-squamous NSCLC. / Stage IIIB or IIIC or Stage IV metastatic NSCLC (according to Edition 8 of the AJCC staging manual) not amenable to curative surgery or definitive chemoradiation. / Absence of sensitising EGFR mutations, and ALK and ROS1 rearrangements, and absence of documented local test result for any other known genomic alteration for which there are locally approved and available targeted first-line therapies. / Must provide tumor sample to determine PD-L1 status, TROP2 status and other biomarkers. / Known tumour PD-L1 expression status defined as TC ≥ 50% / At least one lesion, not previously irradiated that qualifies as a RECIST 1.1 target lesion at baseline / ECOG performance status of 0 or 1 / dequate bone marrow reserve and organ function within 7 days before the first dose of study intervention

Exclusion Criteria:

Prior systemic therapy for advanced/metastatic NSCLC. / Squamous cell histology, or predominantly squamous cell histology NSCLC; mixed small cell lung cancer; NSCLC histology, sarcomatoid variant. / History of another primary malignancy within 3 years / Active or prior documented autoimmune or inflammatory disorders (with exceptions) / Any evidence of severe or uncontrolled systemic diseases, including, but not limited to active bleeding diseases, active infection, active ILD/pneumonitis, cardiac disease. / Has clinically significant third-space fluid retention (for example pleural effusion) and is not amenable for repeated drainage. / History of non-infectious ILD/pneumonitis that required steroids, has current ILD/pneumonitis, or has suspected ILD/pneumonitis that cannot be ruled out by imaging at screening / Has significant pulmonary function compromise, as determined by the investigator / Spinal cord compression, or brain metastases unless participant treated and no longer symptomatic, radiologically stable, and who require no treatment with corticosteroids or anticonvulsants. / History of leptomeningeal carcinomatosis / Known clinically significant corneal disease / Active infection with TB, HBV, HCV, Hepatitis A, or known HIV infection that is not well controlled / History of active primary immunodeficiency

see Link:

clinicaltrials.gov/NCT06357533

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1 „eVOLVE-Meso“

A Phase III, Randomized, Open-Label, Multicenter, Global Study of Volrustomig (MEDI5752) in Combination With Carboplatin Plus Pemetrexed Versus Platinum Plus Pemetrexed or Nivolumab Plus Ipilimumab in Participants With Unresectable Pleural Mesothelioma (eVOLVE-Meso)

Condition: Unresectable Pleural Mesothelioma

Primary Completion Date: 2027-03-15

Phase: III

Intervention / Treatment: DRUG: **Volrustomig/ Pemetrexed/ Carboplatin/ Cisplatin/ Nivolumab/ Ipilimumab**

Inclusion Criteria:

Participant must be ≥ 18 years at the time of screening / Histologically proven diagnosis of pleural mesothelioma with known histology (epithelioid vs. non-epithelioid) / Advanced unresectable disease that cannot be treated with curative surgery (with or without chemotherapy) / WHO/ECOG performance status of 0 or 1 with no deterioration (that is, ECOG PS>1) over the previous 2 weeks prior to day of first dosing / Has measurable disease per modified RECIST1.1 / Has adequate bone marrow reserve and organ function at baseline

Exclusion Criteria:

As judged by the investigator, any condition that would interfere with evaluation of the investigational product or interpretation of participant safety or study results. / Active or prior documented autoimmune or inflammatory disorders / History of another primary malignancy with exceptions. / Uncontrolled intercurrent illness / Tuberculosis, hepatitis B (HBV) or hepatitis C (HCV), human / mmunodeficiency virus (HIV) infection that is not well controlled / Any concurrent chemotherapy, radiotherapy, investigational, biologic, or hormonal therapy for cancer treatment / Untreated or progressive CNS metastatic disease

see Link:

clinicaltrials.gov/NCT06097728

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Universitäres Cancer Center HAMBURG

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A Ph2, Randomized, Blinded, Placebo-Controlled Trial Investigating the Efficacy and Safety of Visugromab Versus Placebo, in Combination With Pembrolizumab, Pemetrexed, and Carboplatin, in 1L Treatment of Participants With Metastatic NSCLC (GDFATHER-NSCLC-01)

Condition: Metastatic Non-Squamous Non-Small Cell Lung Cancer/ Adult Solid Tumor

Primary Completion Date: 2029-03-31

Phase: II

Intervention / Treatment: DRUG: **Matching placebo for visugromab/ Pemetrexed 500 mg/m^2/ Carboplatin AUC 5_BIOLOGICAL: Visugromab/ Pembrolizumab 200 mg Q3W**

Inclusion Criteria:

Histologically confirmed, newly diagnosed stage IV non-squamous NSCLC. / Demonstrated absence of actionable mutations (e.g., EGFR, ALK, among others) that suggest/require treatment with available targeted agent. / Measurable disease determined by the local site Investigator/radiology by their assessment per RECIST v1.1. / Have not received prior systemic treatment for advanced/metastatic NSCLC. Participants who received adjuvant or neoadjuvant therapy are eligible if the adjuvant/neoadjuvant therapy was completed at least 12 months prior to the development of metastatic disease and did not contain any PD 1/PD L1 directed CPI therapy. / Availability of locally determined PD L1 TPS, determined with a test validated for this purpose, from a biopsy obtained after any potential prior systemic treatment for this disease. Participants with PD-L1 TPS ≥ 50% can only be enrolled in case CPI monotherapy is not clinically indicated. / Availability of a tissue/histological biopsy for translational research investigations and Informed Consent Form (ICF) for biopsy release for translational research signed by participant. The biopsy has to be obtained after any potential prior systemic treatment for this disease and be available for shipment. A cytological sample is not accepted. / Age ≥ 18 years on the day of signing the informed consent. / Eastern Cooperative Oncology Group (ECOG) performance status 0-1. / Adequate organ function (bone marrow, hepatic, renal function and coagulation).

Exclusion Criteria:

•Presence of predominantly squamous cell histology or predominantly neuroendocrine histology NSCLC (mixed tumors will be categorized by the predominant cell type) or presence of small cell lung cancer elements (ineligibility independent of percentage). / Any acute or chronic major tissue injury that may require maintained GDF 15 function for tissue protection as per Investigator assessment (diagnosed with myocardial infarction, or liver, kidney or other major organ failure, all within < 3 months prior to planned treatment start). / Major surgery (defined as a surgery which requires general anesthetic and/or involves opening of body cavities), within 4 weeks of the first dose of study drug. / Received potentially curative radiation therapy to the lung that is > 30 Gy within 6 months prior to the first dose of study drug. / Received or completed any focal radiotherapy for symptoms within 28 days of the first dose of study drug. / Expected to require any other form of antineoplastic therapy while on trial. / Clinically active inflammatory bowel disease, active diverticulitis, intra-abdominal abscess, and/or gastrointestinal obstruction. / Known history of prior malignancy with the exception that the participant has undergone potentially curative therapy with no evidence of that disease recurrence for 5 years since initiation of that therapy. / Known or detected clinically active central nervous system (CNS) involvement by NSCLC or other tumors, e.g., with symptomatic metastases and/or carcinomatous meningitis. Participants with CNS involvement may be enrolled with mandatory regular imaging of the brain under protocol-defined conditions. / Have one of the following cardiovascular risk factors: myocardial infarction in the past 3 months before planned treatment start; uncontrolled heart failure; uncontrolled ventricular arrhythmia; QT interval corrected for heart rate using Fridericia's formula interval ≥ 470 ms regardless of sex; peri/myocarditis in the past 3 months before planned treatment start; history of ischemic stroke in the past 3 months before planned treatment start. / Any active autoimmune that has required systemic treatment in the past 3 months before planned treatment start (i.e., with use of disease modifying agents, corticosteroids, or immunosuppressive drugs). / Comedication with metformin in participants with type II diabetes. / Has interstitial lung disease or a history of non-infectious pneumonitis that required systemic steroids or current pneumonitis. / Is pregnant or breastfeeding or expecting to conceive or father children within the projected duration of the trial.

see Link:

clinicaltrials.gov/NCT07098988

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1 „ARTEMIA“

A Randomised, Open-label, Phase 3 Trial Comparing the Efficacy and Safety of OSE2101 Versus Docetaxel in HLA-A2 Positive Patients With Metastatic Non-Small Cell Lung Cancer (NSCLC) With Secondary Resistance to Immune Checkpoint Inhibitor

Condition: Non-Small Cell Lung Cancer

Primary Completion Date: 2027-12-15

Phase: III

Intervention / Treatment: DRUG**: OSE2101/ Docetaxel_** DEVICE**: NGS HLAA2 assay**

Inclusion Criteria:

Male or female, aged ≥ 18 years / Patients expressing HLA-A2 phenotype in blood by pre-screening central laboratory / Patients with histologically or cytologically squamous or non-squamous documented NSCLC, metastatic stage at study entry, not eligible for definite surgery or radiation, without EGFR, ALK and ROS1 gene alterations eligible for targeted therapy; other sensitizing mutations known to be immunosensitive are eligible in case of lack of local access to targeted therapy (i.e.; KRAS G12C and BRAF mutations) after Sponsor's agreement / Patients with secondary resistance to ICI;
Other inclusion and exclusion criteria will apply per protocol.

Exclusion Criteria:

see Link:

clinicaltrials.gov/NCT06472245

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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Randomized, Double Blind, Multicenter Phase 3 Trial of BMS-986489 (BMS-986012+Nivolumab Fixed Dose Combination) in Combination With Carboplatin Plus Etoposide vs Atezolizumab in Combination With Carboplatin Plus Etoposide as First-Line Therapy in Participants With Extensive-Stage Small Cell Lung Cancer (TIGOS).

Condition: Extensive-Stage Small Cell Lung Cancer

Primary Completion Date: 2028-04-06

Phase: III

Intervention / Treatment: DRUG**: Carboplatin/ Etoposide**_BIOLOGICAL: **BMS-986489 (BMS-986012+Nivolumab)/ Atezolizumab**

Inclusion Criteria:

Participants must have diagnosis of Extensive-Stage Small Cell Lung Cancer (ES-SCLC). / Participants must be Healthy enough to do their normal activities with little or no help based on the ECOG performance scale. / Participants must have at least one tumor that can be measured using special imaging techniques like a CT scan or MRI at a site other than the brain and nervous system

Exclusion Criteria:

Participants have already received certain types of treatment for extensive stage small cell lung cancer / Participants have certain health conditions, like spread of small cell lung cancer to the brain that are causing symptoms, certain lung diseases, heart diseases, infections, autoimmune diseases, other cancers, or a type of nerve damage called peripheral sensory neuropathy / Other protocol-defined Inclusion/Exclusion criteria apply.

see Link:

clinicaltrials.gov/NCT06646276

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1 „ARTEMIDE-Lung02“

A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination With Platinum-based Chemotherapy for the First-line Treatment of Patients With Metastatic Squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1

Condition: Non-Small Cell Lung Cancer

Primary Completion Date: 2029-02-05

Phase: III

Intervention / Treatment: DRUG**: Rilvegostomig/ Pembrolizumab/ Carboplatin/ Paclitaxel/ Nab-paclitaxel**

Inclusion Criteria:

Histologically or cytologically documented squamous NSCLC. / Stage IV mNSCLC (based on the American Joint Committee on Cancer Edition 8) not amenable to curative treatment. / Absence of documented tumor genomic mutation results from tests conducted as part of standard local practice in any actionable driver oncogenes for which there are locally approved targeted 1L therapies. / Provision of acceptable tumor sample to confirm tumor PD-L1 expression TC ≥ 1%. / At least one lesion not previously irradiated that qualifies as a RECIST 1.1 TL at baseline and can be accurately measured at baseline as ≥ 10 mm in the longest diameter (except lymph nodes, which must have short axis ≥ 15 mm) with CT or MRI and is suitable for accurate repeated measurements. / Adequate organ and bone marrow function.

Exclusion Criteria:

Presence of small cell and neuroendocrine histology components. / Brain metastases unless asymptomatic, stable, and not requiring steroids or anticonvulsants for at least 7 days prior to randomization. A minimum of 2 weeks must have elapsed between the end of local therapy (brain radiotherapy or surgery) and randomization. Participants must have recovered from the acute toxic effect of radiotherapy (eg, dizziness and signs of increased intracranial pressure) or surgery prior to randomization. / Any prior systemic therapy received for advanced or mNSCLC. / Any prior treatment with an anti-PD-1 or anti-PD-L1 agent. / Any prior exposure to an anti-TIGIT therapy or any other anticancer therapy targeting immune-regulatory receptors or mechanisms. / History of another primary malignancy except for malignancy treated with curative intent with no known active disease ≥ 2 years before the first dose of study intervention and of low potential risk for recurrence. / Active or prior documented autoimmune or inflammatory disorders requiring chronic treatment with steroids or other immunosuppressive treatment. / Active primary immunodeficiency/active infectious disease(s). / Active tuberculosis infection.

see Link:

clinicaltrials.gov/NCT06692738

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG

Universitätsklinikum Hamburg-Eppendorf

1 „SUNRAY-02“

A Phase 3, Multicenter, Double-Blind, Placebo-controlled Study Assessing the Efficacy and Safety of Olomorasib in Combination With Standard of Care Immunotherapy in Participants With Resected or Unresectable KRAS G12C-Mutant, Non-Small Cell Lung Cancer - SUNRAY-02

Condition: Carcinoma, Non-Small Cell Lung

Primary Completion Date: 2029-05

Phase: III

Intervention / Treatment: DRUG**: Olomorasib/ Pembrolizumab/ Durvalumab/ Placebo**

Inclusion Criteria:

Histological or cytological confirmation of NSCLC. . / **Part A:** Clinical Stage II-IIIB (N2) treated with presurgical chemoimmunotherapy, with residual tumor present at time of surgery. Patients with a pathologic complete response are not eligible. . / Pathologic Stage II-IIIB (N2) NSCLC treated with initial upfront resection. . / **Part B:** Clinical Stage III, unresectable NSCLC, without progression on concurrent platinum-based chemoradiotherapy. . / Must have disease with evidence of KRAS G12C mutation. . / Must have known programmed death-ligand 1 (PD-L1) expression . / Must have an ECOG performance status of 0 or 1. . / Able to swallow oral medication. . / Must have adequate laboratory parameters. . / Contraceptive use should be consistent with local regulations for those participating in clinical studies. . / **Women of childbearing potential must:** Have a negative pregnancy test. . / Not be breastfeeding during treatment

Exclusion Criteria:

Have known changes in the EGFR or ALK genes. . / Have another type of cancer that is progressing or required active treatment within the past 3 years before screening. . / Have an active autoimmune disease that required systemic treatment in the past 2 years. Endocrine replacement therapy is allowed. . / Had any immune-related side effect or allergic reaction (Grade 3 or higher) from a previous immunotherapy medicine, or any immune-related side effect greater than Grade 1 that has not resolved. This does not apply for people with hormone-related diseases who are now on stable hormone replacement therapy.

see Link:

clinicaltrials.gov/NCT0890598

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG

Universitätsklinikum Hamburg-Eppendorf

1 „DeLLphi-312“

A Phase 3, Open Label, Multicenter, Randomized Study of First Line Tarlatamab in Combination With Durvalumab, Carboplatin and Etoposide Versus Durvalumab, Carboplatin and Etoposide in Untreated Extensive Stage Small-Cell Lung Cancer (DeLLphi-312)

Condition: Small Cell Lung Cancer, Extensive Stage Small-cell Lung Cancer

Primary Completion Date: 2029-01-04

Phase: III

Intervention / Treatment: DRUG**: Tarlatamab/ Durvalumab/ Carboplatin/ Etoposide**

Inclusion Criteria:

Participant has provided informed consent before initiation of any study-specific activities/procedures. / Age ≥ 18 years or ≥ legal age within the country if it is older than 18 years. / Histologically or cytologically documented ES-SCLC (American Joint Committee on Cancer, 2017, Stage IV SCLC [T any, N any, M1 a/b/c]), or T3 to T4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan. / Measurable disease as defined per RECIST 1.1. / Suitable to receive carboplatin, etoposide and durvalumab regimen as first-line treatment per investigator clinical assessment. / Minimum life expectancy ≥ 12 weeks.

Exclusion Criteria:

Participants can have no history of other malignancy in the last 2 years. / Any symptomatic central nervous system (CNS) metastases, or leptomeningeal disease. / They will have no history of severe or life-threatening events to immune-mediated therapy. / History of arterial thrombosis (eg, stroke or transient ischemic attack) within 6 months prior to first dose of study treatment. / They will have no active autoimmune or inflammatory disorders. / Presence of active human immunodeficiency virus (HIV) or active Hepatitis (B/C) infection. / Evidence or interstitial lung disease (ILD) or active, non-infectious pneumonitis. / History of solid organ transplant. / They will not have had a myocardial infarction and/or symptomatic congestive heart failure (New York Heart Association > class II) within 6 months prior to first dose of study treatment.

see Link:

clinicaltrials.gov/NCT07005128

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG

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1 „RELATIVITY1093“

A Phase 3, Randomized, Open-label Study of Nivolumab + Relatlimab Fixed-dose Combination With Chemotherapy Versus Pembrolizumab With Chemotherapy as First-line Treatment for Participants With Non-squamous (NSQ), Stage IV or Recurrent Non-small Cell Lung Cancer and With Tumor Cell PD-L1 Expression ≥ 1%

Condition: Non-small Cell Lung Cancer

Primary Completion Date: 2030-07-30

Phase: III

Intervention / Treatment: DRUG**: Nivolumab/ Relatlimab/ Pembrolizumab/ Carboplatin/ Pemetrexed/ Cisplatin**

Inclusion Criteria:

Participants must have histologically confirmed Stage IV or recurrent Non-small Cell Lung Cancer (NSCLC) of non-squamous (NSQ) histology with no prior systemic anti-cancer therapy given as primary therapy for advanced or metastatic disease. / Participants must have measurable PD-L1 ≥ 1% Tumor Cell (TC) score by the investigational PD-L1 immunohistochemistry (IHC) assay VENTANA PD-L1 (SP263) CDx Assay conducted by central laboratory during the screening period prior to randomization. / Participants must have measurable disease by computed tomography (CT) or magnetic resonance imaging (MRI) per RECIST v1.1 criteria. / Participants must have an Easter Cooperative Oncology Group (ECOG) performance status of ≤ 1 at screening. / Participants must have a life expectancy of at least 3 months at the time of randomization.

Exclusion Criteria:

Participants must not be pregnant and/or breastfeeding. / Participants with epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or ROS-1 mutations that are sensitive to available targeted inhibitor therapy. Participants with unknown EGFR, ALK, or ROS-1 status are excluded. / Participants with known BRAFV600E mutations, that are sensitive to available targeted inhibitor therapy; participants with known activating rearranged during transfection (RET) mutations or neurotrophic tyrosine receptor kinase (NTRK) fusion gene alterations are excluded. Participants with unknown or indeterminate BRAF mutation, activating RET mutations or NTRK fusion gene alterations are eligible. / Participants must not have untreated central nervous system (CNS) metastases. / Participants must not have leptomeningeal metastases (carcinomatous meningitis). / Participants must not have concurrent malignancy requiring treatment. / Participants must not have an active autoimmune disease. / Participants must not have history of interstitial lung disease or pneumonitis that required oral or intravenous (IV) glucocorticoids to assist with management. / Participants must not have a history of myocarditis. / Participants must not have had prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, or anti-CTLA-4 antibody, or other antibody or drug targeting T-cell co-stimulation or checkpoint pathways. / Other protocol-defined Inclusion/Exclusion criteria apply.

see Link:

clinicaltrials.gov/NCT06561386

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG

Universitätsklinikum Hamburg-Eppendorf

A Phase III, Open-label, Sponsor-blind, Randomized Study of Dato-DXd With or Without Osimertinib Versus Platinum-based Doublet Chemotherapy for Participants With EGFR-mutated Locally Advanced or Metastatic Non-small Cell Lung Cancer Whose Disease Has Progressed on Prior Osimertinib Treatment (TROPION-Lung15)

Condition: Metastatic Non-small Cell Lung Cancer

Primary Completion Date: 2028-05-29

Phase: III

Intervention / Treatment: DRUG: **Dato-DXd/ Osimertinib/ Pemetrexed/ Carboplatin/ Cisplatin**

Inclusion Criteria:

Histologically or cytologically confirmed non-squamous NSCLC. / Must have evidence of documented pre-existing EGFRm information (EGFRm known to be associated with (epidermal growth factor receptor [EGFR] tyrosine kinase inhibitor [TKis] sensitivity [Ex19del, L858R, G719X, S768I, or L861Q], either alone or in combination with other EGFR mutations, which may include T790M). / Documented extra-cranial radiologic progression on prior osimertinib monotherapy (as most recent line of treatment) in the adjuvant, locally advanced, or metastatic setting. / Less than or equal to (<=2) prior lines of EGFR TKIs (osimertinib is the only permitted prior third generation EGFR TKI). . / At least one lesion, not previously irradiated, that qualifies as a RECIST v1.1 TL at baseline and can be accurately measured at baseline. / World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. / Adequate bone marrow reserve and organ function within 7 days before randomization.

Exclusion Criteria:

Use of chemotherapy, vascular endothelial growth factor inhibitor, immunotherapy or any anti-cancer therapy in the metastatic setting. Platinum-based chemotherapy in non-metastatic setting within 12 months prior to randomization. / History of another primary malignancy except for malignancy treated with curative intent with no known active disease within 2 years before the first dose of study intervention. . / Any evidence of severe or uncontrolled systemic diseases, including, but not limited to active bleeding diseases, active infection, active ILD/pneumonitis, cardiac disease. . / Has significant third-space fluid retention (example [eg.], ascites or pleural effusion) as judged by the investigator and is not amenable for required repeated drainage. / History of non-infectious ILD/pneumonitis including radiation pneumonitis that required steroids or drug-induced ILD, has current ILD/pneumonitis, or has suspected ILD/pneumonitis that cannot be ruled out by imaging at screening. / Has severe pulmonary function compromise resulting from intercurrent pulmonary illnesses. / Unstable spinal cord compression and/or unstable brain metastases. / Participants with symptomatic brain metastases (including leptomeningeal involvement). / Clinically significant corneal disease. / Uncontrolled infection requiring systemic antibiotics, antivirals, or antifungals, suspected infections or inability to rule out infections. Use of systemic antibiotics within 14 days of randomization. / Has known human immunodeficiency virus (HIV) infection that is not well controlled.

see Link:

clinicaltrials.gov/NCT06417814

Study Test Center	PI / SC	Phone	E-Mail
Lung Clinic Großhansdorf	Prof. Dr. med. Martin Reck Dr. med. Marlitt Horn	04102 / 601 2101 04102 / 601 2104	m.reck@lungenclinic.de m.horn@lungenclinic.de

A First-In-human Phase I, Non-randomized, Open-label, Multi-center Dose Escalation Trial of BI 764532 Administered by Parenteral Route in Patients With Small Cell Lung Carcinoma and Other Neuroendocrine Neoplasms Expressing DLL3

Condition: Small Cell Lung Carcinoma and Other Neoplasms

Primary Completion Date: 2026-09-01

Phase: I

Intervention / Treatment: DRUG: **BI 764532 - parenteral 1/ BI 764532 - parenteral 2**

Inclusion Criteria:

Signed and dated, written informed consent form (ICF2, ICF3 or ICF4) in accordance with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) - Good Clinical Practice (GCP) and local legislation prior to any trial-specific procedures, sampling, or analyses. / Locally advanced or metastatic cancer not amenable to curative treatment; of following histologies: / Small cell lung carcinoma (SCLC) / Large cells neuroendocrine lung carcinoma (LCNEC) / Neuroendocrine carcinoma (NEC) or small cell carcinoma of any other origin / Tumours must be positive for DLL3 expression (on archived tissue or instudy fresh biopsy) according to central pathology review in order to start BI 764532 / Patients with tumours with mixed histologies for any above type are eligible only if neuroendocrine carcinoma/small tumor cells component is predominant and represent at least 50% of the overall tumour tissue. / For back-fill cohorts only: patient has agreed to and signed an IC to provide mandatory pre-treatment and on-treatment fresh tumor biopsy. / Patient has failed or is not eligible for available standard therapies according to local guidelines. Standard therapies should include at least one line of chemotherapy that should include platinum for patients with small cells carcinoma tumors histologies. / Eastern Cooperative Oncology Group (ECOG) performance status of 0-1. / At least one evaluable lesion outside of CNS as defined per modified Response Evaluation Criteria In Solid Tumors (RECIST) 1.1 / Subjects with brain metastases are eligible provided they meet the following criteria: / Radiotherapy or surgery for brain metastases was completed at least 2 weeks prior to the first administration of BI 764532 / Patient is off steroids for at least 7 days (physiologic doses of steroids are permitted), and the patient is off anti-epileptic drugs for at least 7 days or on stable doses of anti-epileptic drugs for malignant Central Nervous System (CNS) disease.
•Adequate liver, bone marrow and renal organ function Further inclusion criteria apply.

Exclusion Criteria:

see Link:

clinicaltrials.gov/NCT04429087

Study Test Center	PI / SC	Phone	E-Mail
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A Phase 3, Randomized, Double-blind, Placebo- and Active-Comparator-Controlled Clinical Study of Adjuvant V940 (mRNA-4157) Plus Pembrolizumab Versus Adjuvant Placebo Plus Pembrolizumab in Participants With Resected Stage II, IIIA, IIIB (N2) Non-small Cell Lung Cancer (INTerpath-002)

Condition: Non-Small Cell Lung Cancer

Primary Completion Date: 2030-06-25

Phase: III

Intervention / Treatment: Biological**: Intismeran autogene/ Pembrolizumab**_Other: **Placebo**

Inclusion Criteria:

The main inclusion criteria include but are not limited to the following: / Has undergone margin negative, completely resected non-small cell lung cancer (NSCLC), and has pathological Stage II, IIIA, IIIB (N2) squamous or nonsquamous tumor, node, metastasis (TNM) staging per American Joint Committee on Cancer (AJCC) Eighth Edition guidelines. / Has no evidence of disease before randomization. / Has received at least one dose of adjuvant treatment with standard of care platinum doublet chemotherapy. / No more than 24 weeks have elapsed between surgical resection of curative intent and the first dose of pembrolizumab. / Participants who are hepatitis B surface antigen (HBsAg) positive are eligible if they have received hepatitis B virus (HBV) antiviral therapy for at least 4 weeks and have undetectable HBV viral load prior to randomization. / Participants with history of hepatitis C virus (HCV) infection are eligible if HCV viral load is undetectable at screening. / Human immunodeficiency virus (HIV)-infected participants must have well controlled HIV on anti-retroviral therapy (ART).

Exclusion Criteria:

The main exclusion criteria include but are not limited to the following: / Diagnosis of small cell lung cancer (SCLC) or, for mixed tumors, presence of small cell elements, or has a neuroendocrine tumor with large cell components or a sarcomatoid carcinoma. / HIV-infected participants with a history of Kaposi's sarcoma and/or Multicentric Castleman's Disease. / Received prior neoadjuvant therapy for their current NSCLC diagnosis. / Received or is a candidate to receive radiotherapy for their current NSCLC diagnosis. / Received prior therapy with an anti-programmed cell death 1 protein (PD-1), anti-PD-ligand 1 (L1), or anti-PD-L2 agent, or with an agent directed to another stimulatory or coinhibitory T-cell receptor. / Received prior systemic anticancer therapy including investigational agents within 4 weeks before randomization. / Received a live or live-attenuated vaccine within 30 days before the first dose of study intervention. Administration of killed vaccines are allowed. / Has received an investigational agent or has used an investigational device within 4 weeks prior to study intervention administration. / Diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy (in dosing exceeding 10 mg daily of prednisone equivalent) or any other form of immunosuppressive therapy within 7 days prior to the first dose of study medication. / Known additional malignancy that is progressing or has required active treatment within the past 5 years. / Active autoimmune disease that has required systemic treatment in the past 2 years. Replacement therapy (eg, thyroxine, insulin, or physiologic corticosteroid) is allowed. / History of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease. / Active infection requiring systemic therapy.

see Link:

clinicaltrials.gov/NCT06077760

Study Test Center	PI / SC	Phone	E-Mail
Lung Clinic Großhansdorf	Prof. Dr. med. Martin Reck Dr. med. Marlitt Horn	04102 / 601 2101 04102 / 601 2104	m.reck@lungenclinic.de m.horn@lungenclinic.de

A Randomized, Open-Label, Phase 3 Study to Evaluate Zimberelimab and Domvanalimab in Combination With Chemotherapy Versus Pembrolizumab With Chemotherapy for the First-Line Treatment of Patients With Metastatic Non-Small Cell Lung Cancer With No Epidermal Growth Factor Receptor or Anaplastic Lymphoma Kinase Genomic Tumor Aberrations

Condition: Non-Small Cell Lung Cancer

Primary Completion Date: 2028-06

Phase: III

Intervention / Treatment: DRUG: Zimberelimab/ Domvanalimab/ Pembrolizumab/ Carboplatin/ Cisplatin/ Paclitaxel/ Nab-paclitaxel/ Pemetrexed

Inclusion Criteria:

Life expectancy ≥ 3 months. / Pathologically documented NSCLC that meets both of the criteria below: / Have documented evidence of Stage IV NSCLC disease at the time of enrollment (based on American Joint Committee on Cancer (AJCC), Eighth Edition). / Have documented negative test results for epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase (ALK) mutations. / Have no actionable genomic alterations such as ROS proto-oncogene 1 (ROS1), neurotrophic tyrosine receptor kinase (NTRK), proto-oncogene B-raf (BRAF), RET mutations, or other driver oncogenes with approved frontline therapies. / Have not received prior systemic treatment for metastatic NSCLC. / Measurable disease per RECIST v1.1 criteria by investigator assessment. / Eastern Cooperative Oncology Group performance status (ECOG PS) score of 0 or 1. / Have adequate organ functions.

Exclusion Criteria:

Have mixed small-cell lung cancer (SCLC) and NSCLC histology. / Positive serum pregnancy test or individuals who are breastfeeding or have plans to breastfeed during the study period. / Received prior treatment with any anti-PD-1, anti-PD-L1, or any other antibody targeting an immune checkpoint. / Known hypersensitivity to the study drug, its metabolites, or formulation excipient. / Have an active second malignancy or have had an active second malignancy within 3 years prior to enrollment. / Have an active autoimmune disease that required systemic treatment in past 2 years (i.e., with use of disease-modifying agents, corticosteroids, or immunosuppressive drugs). / Are receiving chronic systemic steroids. / Have significant third-space fluid retention. / Have untreated central nervous system (CNS) metastases and/or carcinomatous meningitis. / Active chronic inflammatory bowel disease (ulcerative colitis, Crohn's disease) or gastrointestinal perforation within 6 months of enrollment. / Has a history of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease. / Has had an allogenic tissue/solid organ transplant. / Have received a live-virus vaccination within 30 days of planned treatment start. Seasonal flu and COVID-19 vaccines that do not contain live virus are permitted. / Have known active hepatitis B virus (HBV) or hepatitis C virus (HCV) infection.

see Link:

clinicaltrials.gov/NCT05502237

Study Test Center	PI / SC	Phone	E-Mail
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1 „KRYSTAL-7“

A Phase 2/3 Trial of MRTX849 Monotherapy and in Combination With Pembrolizumab in Patients With Advanced Non-Small Cell Lung cancer With KRAS G12C Mutation

Condition: Advanced or/and Metastatic Non-Small Cell Lung cancer

Primary Completion Date: 2029-10-31

Phase: II/III

Intervention / Treatment: Drug: Adagrasib/ Pembrolizumab

Inclusion Criteria:

Phase 2: Histologically confirmed diagnosis of unresectable or metastatic NSCLC with KRAS G12C mutation and any PD-L1 TPS
Phase 3: Histologically confirmed diagnosis of unresectable or metastatic squamous or nonsquamous NSCLC with KRAS G12C mutation and PD-L1 TPS >=50%
Phase 3: Presence of evaluable or measurable disease per RECIST
Phase 3: CNS Inclusion - Based on screening brain imaging, patients must have one of the following: No evidence of brain metastases Untreated brain metastases not needing immediate local therapy Previously treated brain metastases not needing immediate local therapy

Exclusion Criteria:

Phase 2 and Phase 3: Prior systemic treatment for locally advanced or metastatic NSCLC including chemotherapy, immune checkpoint inhibitor therapy, or a therapy targeting KRAS G12C mutation (e.g., AMG 510).
Phase 2: Active brain metastases
Phase 3: Patients with known central nervous system (CNS) lesions must not have any of the following: Any untreated brain lesions > 1.0 cm in size Any brainstem lesions Ongoing use of systemic corticosteroids for control of symptoms of brain lesions at a total daily dose of > 10 mg of prednisone (or equivalent) prior to randomization. Have poorly controlled (> 1/week) generalized or complex partial seizures, or manifest neurologic progression due to brain lesions notwithstanding CNS-directed therapy Phase 3: Radiation to the lung > 30 Gy within 6 months prior to the first dose of study treatment

see Link:

clinicaltrials.govNCT04613596

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Randomized, Double-Blind, Placebo-Controlled Study of Trilaciclib vs Placebo in Patients With Extensive Stage Small Cell Lung Cancer (ES-SCLC) Receiving Topotecan Chemotherapy

Condition: Extensive-stage Small Cell Lung Cancer

Primary Completion Date: 2027-10-30

Phase: IV

Intervention / Treatment: DRUG: **Trilaciclib/ Placebo/ Topotecan**

Inclusion Criteria:

ES-SCLC with confirmed diagnosis of SCLC by histology or cytology / Progression during or after prior first or second line chemotherapy. First-line regimen must have been a platinum-containing combination. / Measurable or evaluable disease as defined by RECIST v1.1

Exclusion Criteria:

History of topotecan (or other topoisomerase I inhibitor) or trilaciclib treatment for SCLC / Any chemotherapy, immunotherapy, biologic, investigational, or hormonal therapy for cancer treatment within 3 weeks, except for adjuvant hormonal therapy for breast cancer and prostate cancer / Presence of brain metastases/leptomeningeal disease requiring immediate treatment with radiation therapy or steroids / Radiotherapy within 2 weeks / History of ILD/pneumonitis / History of other malignancies, except for curatively treated solid tumors with no evidence of disease for ≥ 2 years or other NCS cancers

see Link:

clinicaltrials.gov/NCT05874401

Study Test Center	PI / SC	Phone	E-Mail
UKSH Lübeck Pulmonology Study Center	Dr. med. Sabine Bohnet Marsha Groth (SC)	0451 500 45003 0451 500 45006	sabine.bohnet@uksh.de Marsha.Groth@uksh.de

A Randomized, Double-blind, Multiregional Phase 3 Study of Ivonescimab Combined With Chemotherapy Versus Pembrolizumab Combined With Chemotherapy for the First-line Treatment of Metastatic Non-small Cell Lung Cancer (HARMONi-3)

Condition: Non-Small Cell Lung Cancer

Primary Completion Date: 2027-12-31

Phase: III

Intervention / Treatment: BIOLOGICAL: **Ivonescimab Injection/ Pembrolizumab Injection**

Inclusion Criteria:

Age ≥ 18 years old at the time of enrollment / Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1 / Expected life expectancy ≥ 3 months / Metastatic (Stage IV) NSCLC / Histologically or cytologically confirmed squamous or non-squamous NSCLC / Recorded measurement of the Tumor Proportion Score (TPS) for PD-L1 expression, irrespective of the PD-L1 expression, prior to randomization / At least one measurable noncerebral lesion according to RECIST 1.1 / No prior systemic treatment for metastatic NSCLC

Exclusion Criteria:

Histologic or cytopathologic evidence of the presence of small cell lung carcinoma / Known actionable genomic alterations (EGFR, ALK, ROS1, and BRAF V600E) or genes for which first-line approved therapies are available. / For non-squamous histology patients, actionable driver mutation testing results are required before randomization. / Has received any prior therapy for NSCLC in the metastatic setting / Tumor invasion, encasement of organs (e.g. heart, trachea, esophagus, central bronchi), or major blood vessels (e.g aorta, central veins), if poses a significant increased risk of bleeding.

see Link:

clinicaltrials.gov/NCT05899608

Study Test Center	PI / SC	Phone	E-Mail
UKSH Lübeck Pulmonology Study Center	Dr. med. Sabine Bohnet Marsha Groth (SC)	0451 500 45003 0451 500 45006	sabine.bohnet@uksh.de Marsha.Groth@uksh.de

Phase 3 Study of Pembrolizumab in Combination With Carboplatin/Taxane (Paclitaxel or Nab-paclitaxel) Followed by Pembrolizumab With or Without Maintenance MK-2870 in the First-line Treatment of Metastatic Squamous Non-small Cell Lung Cancer

Condition: Non-Small Cell Lung Cancer, NSCLC

Primary Completion Date: 2029-01-12

Phase: III

Intervention / Treatment: DRUG: **Carboplatin/ Paclitaxel/ Nab-paclitaxel**_BIOLOGICAL: **Pembrolizuma/ sac-TMT**

Inclusion Criteria:

Histologically or cytologically confirmed diagnosis of squamous non-small cell lung cancer (NSCLC) [Stage IV: M1a, M1b, M1c, American Joint Committee on Cancer Staging Manual, version 8] / Measurable disease per Response Evaluation Criteria in Solid Tumours (RECIST) 1.1 as assessed by the local site investigator/radiology / Has life expectancy ≥3 months / Has Eastern Cooperative Oncology Group Performance Status (ECOG PS) score of 0 or 1 assessed within 7 days prior to allocation / Archival tumor tissue sample or newly obtained core, incisional, or excisional biopsy of a tumor lesion not previously irradiated has been provided / Human immunodeficiency virus (HIV)-infected participants must have well controlled HIV on antiretroviral therapy (ART) / Participants who are hepatitis B surface antigen (HBsAg)-positive are eligible if they have received hepatitis B virus (HBV) antiviral therapy for at least 4 weeks and have undetectable HBV viral load before allocation / Participants with history of hepatitis C virus (HCV) infection are eligible if HCV viral load is undetectable at screening / Participants who have adverse events (AEs) due to previous anticancer therapies must have recovered to Grade ≤1 or baseline (participants with endocrine-related AEs who are adequately treated with hormone replacement are eligible). Note: Participants with Grade =2 neuropathy are eligible / Has adequate organ function / For Maintenance only (prior to randomization): is without disease progression of their NSCLC, as determined by BICR using RECIST 1.1 after completion of study-specified Induction with an evaluable scan at Week 12 or most recent scan before randomization / For Maintenance only (prior to randomization): has ECOG PS of 0 or 1 as assessed at the Prerandomization Visit

•For Maintenance only (prior to randomization): all AEs (with the exception of alopecia, Grade 2 fatigue, and Grade ≤2 endocrine-related AEs requiring treatment or hormone replacement) have recovered

Exclusion Criteria:

see Link:

clinicaltrials.gov/NCT06422143

Study Test Center	PI / SC	Phone	E-Mail
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1 „COCOON“

A Phase 2, Open-Label, Randomized Trial Evaluating the Impact of Enhanced Versus Standard Dermatologic Management on Selected Dermatologic Adverse Events Among Patients With Locally Advanced or Metastatic EGFR-Mutated NSCLC Treated First-Line With Amivantamab + Lazertinib

Condition: Carcinoma, Non-Small Cell Lung

Primary Completion Date: 2027-05-31

Phase: II

Intervention / Treatment: DRUG: **Amivantamab IV/ Amivantamab SC/ Lazertinib/ Doxycycline/ Minocycline/ Clindamycin/ Chlorhexidine/ Zinc gluconate/ Propranolol/ Timolol/ Clobetasol**_OTHER: **Noncomedogenic skin moisturizer/ Ruxolitinib/ Tacrolimus**

Inclusion Criteria:

Have histologically or cytologically confirmed, locally advanced or metastatic non-small cell lung cancer (NSCLC); Is treatment naive and not amenable to curative therapy including surgical resection or (chemo) radiation. Adjuvant or neoadjuvant therapy for Stage I, Stage II or Stage IIIA disease is allowed if last dose administered more than 12 months prior to the development of locally advanced or metastatic disease / Have a tumor that harbors an epidermal growth factor receptor (EGFR) Exon 19del or Exon 21 L858R substitution, as detected by an Food and Drug Administration (FDA)-approved or other validated test in a clinical laboratory improvement amendments (CLIA)-certified laboratory (sites in the United States) or an accredited local laboratory (sites outside of the United States) in accordance with site standard-of-care / A participant with asymptomatic or previously treated and stable brain metastases may participate in this study. Participants with a history of symptomatic brain metastases must have had all lesions treated as clinically indicated (that is, no current indication for further definitive local therapy). Any definitive local therapy to brain metastases must have been completed at least 14 days prior to randomization, and the participant can be receiving no greater than 10 milligram (mg) prednisone or equivalent daily for the treatment of intracranial disease / Can have prior or concurrent second malignancy (other than the disease under study) which natural history or treatment is unlikely to interfere with any study endpoints, safety, or the efficacy of the study treatment(s). For the amivantamab SC expansion cohort: Due to the increased risk of skin cancer with ruxolitinib, participants with any prior or concurrent skin malignancies will be excluded / **Sub-study:** Participants must have new-onset or persistent (defined as non-responsive to standard of care [SoC]) Grade >=2 specific DAEIs of the scalp, face, or body, as defined by NCI-CTCAE Grading v5.0 for DAEIs (excluding paronychia)

Exclusion Criteria:

see Link:

clinicaltrials.gov/NCT06120140

Study Test Center	PI / SC	Phone	E-Mail
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1 „TROPION-Lung08“

A Randomized, Open-label, Phase 3 Trial of Dato-DXd Plus Pembrolizumab vs Pembrolizumab Alone in Treatment-naïve Subjects With Advanced or Metastatic PD-L1 High (TPS ≥50%) Non-small Cell Lung cancer Without Actionable Genomic Alterations (TROPION-Lung08)

Condition: Metastatic Non-mall Cell Lung cancer
Primary Completion Date: 2028-02-29
Phase: III
Intervention/ Treatment: Drug (**Datopotamab Deruxtecan/ Pembrolizumab**)

Inclusion Criteria:
Participants eligible for inclusion in the study must meet all inclusion criteria within 28 days of randomization into the study./ Sign and date the Tissue Screening and Main Informed Consent Forms, prior to the start of any study-specific qualification procedures./ Adults ≥18 years or the minimum legal adult age (whichever is greater) at the time of informed consent./ Histologically documented NSCLC that meets all of the following criteria:/ Stage IIIB or IIIC disease and not candidates for surgical resection or definitive chemoradiation, or Stage IV NSCLC disease at the time of randomization (based on the American Joint Committee on cancer, Eighth Edition). Participants with early-stage NSCLC who have relapsed should be restaged during screening to ensure their eligibility for the study./ Documented negative test results for epidermal growth factor receptor (EGFR), lymphoma kinase (ALK), and proto-oncogene1 (ROS1) actionable genomic alterations based on analysis of tumor tissue./ No known actionable genomic alterations in neurotrophic tyrosine receptor kinase (NTRK), proto-oncogene B-raf (BRAF), rearranged during transfection (RET), mesenchymal-epithelial transition factor (MET), or other actionable driver kinases with locally approved therapies./ Has provided a formalin-fixed tumor tissue sample for the measurement of trophoblast cell surface protein 2 (TROP2) protein expression and for the assessment of other exploratory biomarkers./ Tumor has high programmed death receptor-1 (PD-L1) expression (TPS ≥50%) as determined by PD-L1 immunohistochemistry (IHC) 22C3 pharmDx assay by central testing (minimum of 6 slides)./ Has an adequate treatment washout period before Cycle 1 Day 1.
Measurable disease based on local imaging assessment using RECIST Version 1.1.
Has left ventricular ejection fraction (LVEF) ≥50% by either an echocardiogram (ECHO) or multigated acquisition scan (MUGA) within 28 days before randomization.
Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0 or 1 at screening.
Has a life expectancy of at least 3 months.
Adequate bone marrow function within 7 days before randomization.

Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT05215340

Study Test Center	PI / SC	Phone	E-Mail
Lung Clinic Großhansdorf	Prof. Dr. med. Martin Reck Dr. med. Marlitt Horn	04102 / 601 2101 04102 / 601 2104	m.reck@lungenclinic.de m.horn@lungenclinic.de

Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Phase 3 Open-Label, Randomized, Controlled, Global Study of Telisotuzumab Vedotin (ABBV-399) Versus Docetaxel in Subjects With Previously Treated c-Met Overexpressing, EGFR Wildtype, Locally Advanced/Metastatic Non-Squamous Non-Small Cell Lung cancer

Condition: Non Small Cell Lung cancer
Primary Completion Date: 2028-03-21
Phase: III
Intervention/ Treatment: Drug (**Docetaxel**), Biological (**Telisotuzumab Vedotin**)

Inclusion Criteria:
Participants must have c-Met overexpressing non-small cell lung cancer (NSCLC) as assessed by an AbbVie designated immunohistochemistry (IHC) laboratory using the VENTANA MET (SP44) RxDx assay./ Archival or fresh tumor material must be submitted for assessment of c-Met levels during the Pre-Screening period. Tumor material from the primary tumor site and/or metastatic sites are allowed.If a participant was prescreened for Study M14-239 but did not enroll, tumor material previously submitted for Study M14-239 may be used for Study M18-868 Pre-Screening upon confirmation from AbbVie that sufficient evaluable tumor material is available (Except China)./ A histologically documented non-squamous cell NSCLC that is locally advanced or metastatic./ A known epidermal growth factor receptor (EGFR) activating mutation status./ Actionable alterations in genes other than EGFR ./ Measurable disease per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1./ An Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 1./ Have received no more than 1 line of prior systemic cytotoxic chemotherapy in the locally advanced or metastatic setting.Neoadjuvant and adjuvant systemic cytotoxic chemotherapy will count as a prior line for eligibility purposes if progression occurred within 6 months of the end of therapy./ Have progressed on at least 1 line of prior therapy for locally advanced/metastatic NSCLC:/ Participants WITHOUT an actionable gene alteration: must have progressed on (or be considered ineligible for) platinum-based chemotherapy and immune checkpoint inhibitor (as monotherapy or in combination with chemotherapy)./ Participants WITH an actionable gene alteration for which immune checkpoint inhibitor therapy is not SoC (e.g., anaplastic lymphoma kinase [ALK] translocation): must have progressed on (or be considered ineligible for) anti-cancer therapy targeting driver gene alterations and platinum-based chemotherapy./ Participants with actionable gene alterations for which immune checkpoint inhibitor is SoC must have also progressed on (or be considered ineligible for) immune checkpoint inhibitor (as monotherapy or in combination with chemotherapy)./ Must be considered appropriate for docetaxel therapy based on the assessment of the treating physician./ Participants with metastases to the central nervous system (CNS) are eligible only after definitive therapy (such as surgery or radiotherapy) is provided and:/ There is no evidence of progression of CNS metastases at least 2 weeks after definitive therapy./ They are asymptomatic and off or on a stable or reducing dose of systemic steroids and/or anticonvulsants for at least 2 weeks prior to first dose of telisotuzumab vedotin.

Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT04928846

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

1 „LuCa-MERIT-1“, BNT 116-01

LuCa-MERIT-1: First-in-human, Open Label, Phase I Dose Confirmation Trial Evaluating the Safety, Tolerability and Preliminary Efficacy of BNT116 Alone and in Combinations in Patients With Advanced Non-small Cell Lung cancer

Condition: Non-Small Cell Lung cancer
Primary Completion Date: 2027-04
Phase: I
Intervention/ Treatment: Biological (**BNT116/ Cemiplimab**) DRUG (**Docetaxel/ Carboplatin/ Paclitaxel**)

Inclusion Criteria:
Patients must have histologically confirmed NSCLC and measurable disease by RECIST v1.1. Note: Patients in Cohort 1 and Cohort 5 do not have to present with measurable disease.
Patients in Cohorts 1 to 4 and Cohort 7 must present with unresectable Stage III or metastatic Stage IV NSCLC by American Joint Commission on cancer (AJCC) cancer Staging Manual, Eighth Edition.
Patients in Cohort 5 must present with unresectable Stage III NSCLC by AJCC cancer Staging Manual, Eighth Edition before receiving pre-trial chemoradiotherapy.
Patients in Cohort 6 with the initial diagnosis of resectable Stage II and Stage III NSCLC by AJCC cancer Staging Manual, Eighth Edition.
Patients in Cohorts 2, 4, 5, and 6 must be able to tolerate (additional) anti-PD-1 therapy (i.e., did not permanently discontinue anti-programmed death protein 1 [PD-1] / programmed death ligand 1 [PD-L1] therapy due to toxicity).
Patients in Cohorts 2, 3, 6, and 7 must have an Eastern Cooperative Oncology Group performance status (ECOG-PS) ≤1. Patients in Cohort 1, 4, and 5 with an ECOG-PS of 0-2 are eligible.
Cohort-specific Inclusion Criteria:

Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT05142189

Study Test Center	PI / SC	Phone	E-Mail
UKE Medical Oncology	Dr. med. Franziska Westendorf Marc Hartung (SC)	0152-228 277 89 0152-228 39 570	Franziska.Westendorf@uke.de m.hartung@uke.de

Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

1 „PACE-LUNG“

Additional chemotherapy for EGFRm patients with the continued presence of plasma ctDNA EGFRm at week 3 after start of osimertinib 1st-line treatment

Condition: NSCLC Stage IIIB or IV

Primary Completion Date: 2026-07-06

Phase: II

Intervention/ Treatment: DRUG: **Osimertinib, Pemetrexed, Cisplatin, Carboplatin**

Inclusion Criteria:

Pre-Screening Phase: 1. Provision of written informed consent for the pre-screening phase. / 2. Age ≥ 18 years / 3. Histologically confirmed stage IIIB or IV NSCLC / 4. Tumor positive for Ex19del or L858R EGFR mutation assessed according to local standard. / 5. Planned treatment with osimertinib 80mg/d 1st-line as SoC or ongoing treatment for a maximum of 28 days / 6. Available radiographic chest and abdominal CT or MRI scans performed up to 42 days before initial osimertinib treatment / 7. Previously untreated with systemic treatment given as primary therapy for advanced or metastatic disease, except for osimertinib for a maximum of 28 days (see above) / 8. At least one measurable site of disease as defined by RECISTv1.1 criteria / 9. Female subjects of childbearing potential (WOCBP) should be using highly effective contraceptive measures and must have a negative urine or serum pregnancy test within 7 days prior to start of study treatment and must not be breast-feeding prior to start of trial. / 10. Non-child-bearing potential must be evidenced by fulfilling **one of the following criteria** at screening: • Post-menopausal defined as aged more than 50 years and amenorrheic for at least 12 months following cessation of all exogenous hormonal treatments / • Women under 50 years old would be considered postmenopausal if they have been amenorrheic for 12 months or more following cessation of exogenous hormonal treatments and with LH and FSH levels in the post-menopausal range for the institution. / • Documentation of irreversible surgical sterilisation by hysterectomy, bilateral oophorectomy or bilateral salpingectomy but not tubal ligation

Treatment Phase: 1. Provision of informed consent for the screening and treatment phase prior to any study specific procedures, including screening evaluations that are not SoC. / 2. Persistent mEGFR ctDNA signal 21 to 28 days after osimertinib initiation for advanced of metastatic ex19del or L858R EGFR mutation positive NSCLC as assessed by a liquid biopsy during the pre-screening phase of the trial in the central laboratory. / 3. ECOG performance status 0-2. / 4. The patient is willing and able to comply with the protocol for the duration of the study, including hospital visits for treatment and scheduled follow-up visits and examinations. / 5. Osimertinib no longer than 10 weeks before start of chemotherapy in the treatment phase

Exclusion Criteria:

see Link:

clinicaltrials.gov/NCT05281406

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG

Universitätsklinikum Hamburg-Eppendorf

1 „eVOLVE-Lung02“

A Phase III, Two-Arm, Parallel, Randomized, Multi-Center, Open-Label, Global Study to Determine the Efficacy of Volrustomig (MEDI5752) Plus Chemotherapy Versus Pembrolizumab Plus Chemotherapy for First-Line Treatment of Patients With Metastatic Non-Small Cell Lung cancer (mNSCLC).

Condition: Metastatic Non-Small Cell Lung cancer
Primary Completion Date: 2028-05-30
Phase: III
Intervention/ Treatment: DRUG: **Volrustomig/ Pembrolizumab/ Carboplatin/ Paclitaxel/ Pemetrexed**

Inclusion Criteria:
Histologically or cytologically documented squamous or non-squamous NSCLC.
Stage IV NSCLC (according to Version 8 of the IASLC Staging Manual in Thoracic Oncology 2016), not amenable to curative surgery or radiation.
Absence of sensitizing EGFR mutations and ALK and ROS1 rearrangements.
Absence of documented tumor genomic alteration results from tests conducted as part of standard local practice in any other actionable driver oncogenes for which there are locally approved targeted first-line therapies.
Exclusion Criteria:
Mixed small-cell lung cancer and NSCLC histology or sarcomatoid variant. Rare subtypes are excluded./ Spinal cord compression.
Symptomatic brain metastases. Brain metastases may be treated or untreated, but participants must be asymptomatic and off steroids for at least 14 days prior to start of study intervention. A minimum of 2 weeks must have elapsed between the end of whole brain radiotherapy and study enrollment.
History of another primary malignancy except for:
-Malignancy treated with curative intent with no known active disease ≥ 2 years before the first dose of study intervention and of low potential risk for recurrence.
-Adequately treated non-melanoma skin cancer or lentigo maligna without evidence of disease.
-Adequately treated carcinoma in situ without evidence of disease.
-As judged by the investigator, any condition that would interfere with evaluation of the study intervention or interpretation of participant safety or study results.
see Link:

clinicaltrials.gov/NCT05984277

Study Test Center	PI / SC	Phone	E-Mail
Kath. Marienkrankenhaus gGmbH (Hamburg)	Dr. med. P.Ebeling Brigitta Bergel (SC)	040 / 2546 2502 040 / 2546 2118	ebeling.innere@marienkrankenhaus.org bergel.innere@marienkrankenhaus.org

Universitäres Cancer Center HAMBURG
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1 „MO41552“

Randomized, Open Label, Multicenter, Phase III Study of Entrectinib Versus Crizotinib in Patients With Locally-Advanced or Metastatic Non-Small Cell Lung cancer Harboring ROS1 Gene Rearrangements With and Without Central Nervous System Metastases

Condition: Carcinoma, Non-Small Cell Lung
Primary Completion Date: 2027-12-01
Phase: III
Intervention/ Treatment: DRUG: **Entrecitinib, Crizotinib**

Inclusion Criteria:
Histologically or cytologically-confirmed diagnosis of advanced or recurrent (Stage IIIB/C not amenable for radical treatment) or metastatic (Stage IV) NSCLC that harbors a documented ROS1 gene rearrangement. / No prior treatment with a ROS1 tyrosine kinase inhibitor, chemotherapy or other systemic therapy for advanced or recurrent (Stage IIIB/C not amenable for radical treatment) or metastatic (Stage IV) NSCLC / Prior radiotherapy is allowed if more than 14 days have elapsed between the end of treatment and randomization / Measurable systemic disease according to RECIST v1.1 / Participants with measurable and non-measurable CNS lesions per RECIST v1.1, including leptomeningeal carcinomatosis / Life expectancy of at least 12 weeks / Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1 or 2 / Adequate hematologic, renal, liver functions /
Participants must have recovered from effects of any major surgery or significant traumatic injury at least 28 days before the first dose of study treatment
Ability to swallow entrectinib and crizotinib intact without chewing, crushing, or opening the capsules
For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods with a failure rate of <1% per year during the treatment period and for up to 5 weeks after the last dose of entrectinib or for at least 90 days after the last dose of crizotinib
For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating sperm.

Exclusion Criteria:
Prior treatment with a ROS1 tyrosine kinase inhibitor, chemotherapy or other systemic therapy for advanced or recurrent (Stage IIIB/C not amenable for radical treatment) or metastatic (Stage IV) NSCLC
NCI-CTCAE v5.0 Grade 3 or higher toxicities due to any prior therapy (excluding alopecia, fatigue, nausea and lack of appetite), which have not shown improvement and are strictly considered to interfere with current study drug / History of recent (within the past 3 months) symptomatic congestive heart failure or ejection fraction ≤ 50% observed during screening for the study
History of prolonged corrected QTc interval / Peripheral sensory neuropathy ≥ Grade 2 / Known interstitial lung disease, interstitial fibrosis, or history of tyrosine kinase inhibitor-induced pneumonitis / Previous malignancy within the past 3 years / Incomplete recovery from any surgery prior to the start of study treatment / Active GI disease (e.g., Crohn's disease, ulcerative colitis or short gut syndrome) or other malabsorption syndrome that would reasonably impact drug absorption / History of prior therapy-induced pneumonitis / Any condition (in the past 3 months) e.g., myocardial infarction, unstable angina, coronary/peripheral artery bypass graft, cerebrovascular accident or transient ischemic attack, stroke, symptomatic bradycardia, or uncontrolled arrhythmias requiring medication
Known active infections (bacterial, fungal or viral, including human immunodeficiency virus positive) / History of hypersensitivity to any of the additives in the entrectinib and/or crizotinib drug formulations / Pregnant or lactating women / Known human immunodeficiency virus (HIV) positivity or acquired immunodeficiency syndrome (AIDS)-related illness /
Any clinically significant concomitant disease or condition that could interfere with, or for which the treatment might interfere with, the conduct of the study or the absorption of oral medications.

see Link:

clinicaltrials.gov/NCT04603807

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

1 „Antelope“

This is an open-label randomized, controlled, multicenter, phase II trial with two arms. Patients with metastatic TTF-1 negative, treatment-naive lung adenocarcinoma without actionable genomic alterations are randomized in a 1:1 manner to investigate the efficiency of atezolizumab, carboplatin and nab-paclitaxel (Arm A) versus pembrolizumab, cis-/carboplatin and pemetrexed (Arm B) as first-line treatment.

Condition: Metastatic Non-small Cell Lung cancer Metastatic
Primary Completion Date: 2025-10
Phase: II
Intervention/ Treatment: DRUG: **Atezolizumab/ Nab paclitaxel/ Carboplatin/ Pembrolizumab/ Cisplatin/ Carboplatin/ Pemetrexed**

Inclusion Criteria:
Patient has provided written informed consent/ Patient* 18 years or older at time of signing the informed consent form/ Histologically or cytologically confirmed metastatic stage IV non-squamous NSCLC Negative local testing for TTF-1/ Negative molecular testing for EGFR mutations and ALK rearrangements (tested locally)/ PD-L1 tumor proportion score (TPS) < 50%, tested locally by QUiP®-certified immunohistochemistry/ ECOG performance status ≤ 1/ Measurable lesions according to RECIST v1.1/ Life expectancy ≥ 12 weeks/ Adequate hepatic, renal and bone marrow function / Hemoglobin ≥ 8.0 g/dL/ Absolute neutrophil count ≥ 1.5 x 109/L/ Platelets ≥ 100 x 109/L/ Calculated creatine clearance ≥ 50 mL/min as determined by the Cockcroft-Gault equation and/or creatinin ≤ 1,5x upper limit of normal (ULN)/ Serum bilirubin ≤ 1.5 x institutional ULN/ AST/ ALT and alkaline phosphatase ≤ 2.5 x ULN / International normalized ratio (INR)/ Activated partial thromboplastin time (aPTT) ≤1.5 × ULN unless participant is receiving anticoagulant therapy as long as PTT is within therapeutic range of intended use of anticoagulants/ The patient is willing and able to comply with the protocol for the duration of the study, including hospital visits for treatment and scheduled follow-up visits and examinations.
Female patients who are considered as woman of childbearing potential (WOCBP) must use any contraceptive method with a failure rate of less than 1% per year during the treatment as well as up to 6 months after the last dose of study treatment. Male patients who are sexually active with WOCBP must use any contraceptive method with a failure rate of less than 1% per year during the treatment as well as at least 6 months after the last dose of IMP. Female patients who are not of childbearing potential (i.e., who are postmenopausal or surgically sterile) as well as azoospermic male patients do not require contraception
see Link:

clinicaltrials.gov/NCT05689671

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

1 „TACTI-004“

TACTI-004, a Double-Blinded, Randomized Phase 3 Trial in Patients With Advanced/Metastatic Non-Small Cell Lung Cancer (NSCLC) Receiving Eftilagimod Alfa (MHC Class II Agonist) in Combination With Pembrolizumab (PD-1 Antagonist) and Chemotherapy.

Condition: Advanced/Metastatic Non-small Cell Lung cancer Metastatic
Primary Completion Date: 2027-06
Phase: III
Intervention/ Treatment: DRUG: **Carboplatin plus paclitaxel/cisplatin or carboplatin + pemetrexed**_BIOLOGICAL: **Eftilafimod alfa/pembrolizumab (KEYTRUDA®)**_ OTHER: **Placebo**

Inclusion Criteria:
Patient has provided written informed consent/ Patient* 18 years or older at time of signing the informed consent form/ Histologically or cytologically confirmed metastatic stage IV non-squamous NSCLC Negative local testing for TTF-1/ Negative molecular testing for EGFR mutations and ALK rearrangements (tested locally)/ PD-L1 tumor proportion score (TPS) < 50%, tested locally by QUiP®-certified immunohistochemistry/ ECOG performance status ≤ 1/ Measurable lesions according to RECIST v1.1/ Life expectancy ≥ 12 weeks/ Adequate hepatic, renal and bone marrow function / Hemoglobin ≥ 8.0 g/dL/ Absolute neutrophil count ≥ 1.5 x 109/L/ Platelets ≥ 100 x 109/L/ Calculated creatine clearance ≥ 50 mL/min as determined by the Cockcroft-Gault equation and/or creatinin ≤ 1,5x upper limit of normal (ULN)/ Serum bilirubin ≤ 1.5 x institutional ULN/ AST/ ALT and alkaline phosphatase ≤ 2.5 x ULN / International normalized ratio (INR)/ Activated partial thromboplastin time (aPTT) ≤1.5 × ULN unless participant is receiving anticoagulant therapy as long as PTT is within therapeutic range of intended use of anticoagulants/ The patient is willing and able to comply with the protocol for the duration of the study, including hospital visits for treatment and scheduled follow-up visits and examinations.

Female patients who are considered as woman of childbearing potential (WOCBP) must use any contraceptive method with a failure rate of less than 1% per year during the treatment as well as up to 6 months after the last dose of study treatment. Male patients who are sexually active with WOCBP must use any contraceptive method with a failure rate of less than 1% per year during the treatment as well as at least 6 months after the last dose of IMP. Female patients who are not of childbearing potential (i.e., who are postmenopausal or surgically sterile) as well as azoospermic male patients do not require contraception

see Link:

clinicaltrials.gov/NCT06726265

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Phase III, Open-label, Randomised Study of Osimertinib With or Without Datopotamab Deruxtecan (Dato-DXd), as First-line Treatment in Participants With Epidermal Growth Factor Receptor (EGFR) Mutation-positive, Locally Advanced or Metastatic Non-small Cell Lung Cancer

Condition: Non-small Cell Lung cancer
Primary Completion Date: 2028-03-21
Phase: III
Intervention/ Treatment: DRUG: **Osimertinib/ Datopotamab Deruxtecan**

Inclusion Criteria:
Participant must be ≥ 18 years. / Type of Participant and Disease Characteristics / Histologically or cytologically documented nonsquamous NSCLC. NSCLC of mixed histology is allowed if adenocarcinoma is the predominant histology. Mixed small-cell lung cancer and NSCLC histology, and sarcomatoid variant of NSCLC is ineligible. / Stage IIIB or IIIC or Stage IV metastatic NSCLC or recurrent NSCLC (based on the American Joint Committee on Cancer Edition 8) not amenable to curative surgery or definitive chemoradiation at the time of randomisation. / Participants must not have received prior EGFR TKIs or other systemic therapy for Stage IIIB, IIIC or IV NSCLC. / The tumour harbors at least 1 of the 2 common EGFR mutations known to be associated with EGFR-TKI sensitivity (Ex19del or L858R), either alone or in combination with other genomic alterations, which may include EGFR T790M, assessed by a CLIA-certified (US sites) or an accredited (outside of the US) local laboratory or by central prospective tissue testing. / For participants enrolled in randomisation period, mandatory provision of an unstained, archival tumour tissue sample in a quantity sufficient to allow for central confirmation of the EGFR mutation status. / WHO performance status of 0 or 1. / At least one lesion not previously irradiated that qualifies as a RECIST 1.1 TL at baseline and can be accurately measured at baseline as ≥10 mm in the longest diameter (except lymph nodes, which must have short axis ≥15 mm) with CT or MRI and is suitable for accurate repeated measurements. / Adequate bone marrow reserve and organ function within 7 days before the first dose of study intervention. / Sex and Contraceptive/Barrier Requirements / Contraceptive use by males or females should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies. / Other Inclusion Criteria / All races, gender and ethnic groups are eligible for this study.
see Link:

clinicaltrials.gov/NCT06350097

Study Test Center	PI / SC	Phone	E-Mail
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Head and neck tumors

continue...

Contact at UCC Hamburg
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2 „NPC-NIVO“

The purpose of this study is to assess whether the addition of the immune checkpoint inhibitor Nivolumab to induction chemotherapy will increase the percentage of patients with a complete response on MRI and PET after 3 cycles of induction therapy.

Condition: Nasopharyngeal Carcinoma, Nasopharyngeal cancer, Nasopharyngeal Neoplasms, Nasopharynx cancer
Primary Completion Date: 2026-01-29
Phase: II
Intervention/ Treatment: DRUG: **Nivolumab/ Cisplatin/ 5-Fluorouracil/ Gemcitabine/ Interferon beta-1a**_RADIATION: **Radiotherapy**_
PROCEDURE: **MRI/ PET**_ BEHAVIORAL: **Patient-Reported Outcomes**

Inclusion Criteria:
Histologically confirmed new diagnosis of nasopharyngeal carcinoma according to the current WHO classification in children and adolescents, aged between 3 years and 17 years, OR histologically confirmed new diagnosis of EBV-positive nasopharyngeal carcinoma, WHO stage II or III, in subjects ≥ 18 years /
Stage II or higher in patients ≤ 25 years of age, stage III and IV in patients > 25 years of age (AJCC, 8th edition) / Measurable disease by MRI per RECIST 1.1 criteria /
Sufficient tumor tissue to be sent for central review, including PD-L1 staining, either as 1 or 2 full blocks (preferred) or a minimum of 25 slides, obtained from core biopsy, punch biopsy, excisional biopsy or surgical specimen / Written informed consent by legal guardians (if patient not ≥ 18 years) and patient prior to study participation
see Link:

clinicaltrials.gov/NCT06019130

Study Test Center	PI / SC	Phone	E-Mail
UKE Head and Neck	Dr. med. Philippe Schafhausen Annette Weber (SC)	0152-228 160 55 0152-228 178 00	schafhausen@uke.de annette.weber@uke.de

Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

An Open Label Phase II Randomized Trial of BNT113 in Combination With Pembrolizumab Versus Pembrolizumab Monotherapy as a First Line Therapy in Patients With Unresectable Recurrent, or Metastatic Head and Neck Squamous Cell Carcinoma (HNSCC) Which is Positive for Human Papilloma Virus 16 (HPV16+) and Expresses PD-L1

Condition: Unresectable Head and Neck Squamous Cell Carcinoma, Metastatic Head and Neck cancer, Recurrent Head and Neck cancer
Primary Completion Date: 2028-05
Phase: II
Intervention/ Treatment: BIOLOGICAL: BNT113/ Pembrolizumab

Inclusion Criteria:
Pre-screening phase (optional - patients can alternatively perform tumor biomarker testing as part of the main screening phase): / Patients must sign the written pre-screening informed consent form (ICF) before any pre-screening procedures. / Patients must have histologically confirmed recurrent or metastatic HNSCC with no prior systemic anticancer therapy administered in the recurrent or metastatic (R/M) setting. / Patients have a clinical situation at a relatively high risk of developing R/M disease. / Patients do not meet any exclusion criteria for the main clinical trial, except for time-dependent (e.g., prior systemic treatment in the prior 6 months) or potentially reversible conditions that in the opinion of the investigator will be resolved prior to potential enrollment into the main phase.
Main trial: Patients must sign the written informed consent form before any screening procedure. Informed consent must be documented before any trial-specific screening procedure is performed./ Patients must be aged ≥18 years on the date of signing the informed consent. / Patients must be willing and able to comply with scheduled visits, treatment schedule, laboratory tests, and other requirements of the trial. / Patients who present histologically confirmed recurrent or metastatic HPV16+ HNSCC that is considered incurable by local therapies. / Patients who have a tumor that expresses PD-L1 [CPS ≥1] as determined by the approved test PD-L1 IHC 22C3 pharmDx kit performed and evaluated according to the manufacturer's specifications and relevant regulatory approvals. / The eligible primary tumor locations are oropharynx, oral cavity, hypopharynx, and larynx. / Patients must not have had prior systemic anticancer therapy administered in the incurable recurrent or metastatic setting. Systemic therapy which was completed more than 6 months prior to randomization, if given as part of multimodal treatment for locally advanced disease, is allowed. / Patients who have measurable disease based on RECIST 1.1 as determined by the site and confirmed by BICR. Tumor lesions situated in a previously irradiated area may be considered measurable, if progression has been demonstrated in such lesions disease by RECIST 1.1. / Patients have Eastern Cooperative Oncology Group (ECOG) performance status ≤1./ Patients have adequate bone marrow function as defined by hematological parameters./ Patients have adequate hepatic function. / Patients should have adequate kidney function, assessed by the estimated glomerular filtration rate (eGFR) ≥30 mL/min/1.73m^2 using the Chronic Kidney Disease Epidemiology Collaboration (CPK-EPI) equation. / Patients should be stable with adequate coagulation, as determined by the investigator. / All patients must provide a tumor tissue sample (formalin fixed paraffin embedded [FFPE] blocks or both slides and curls) from archival tissue, or fresh biopsy if a biopsy is performed as part of the patient's standard clinical practice before the first dose of trial treatment. / Women of childbearing potential (WOCBP) must not be pregnant. WOCBP, male patients who are sexually active with WOCBP and female partners of male patients should use a highly effective method of contraception up to at least 6 months after receiving the last dose of trial treatment, and should agree not to donate eggs (ova, oocytes) or sperm.
see Link:

clinicaltrials.gov/NCT04534205

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Evaluate Dostarlimab as Sequential Therapy After Chemoradiation in Participants With Locally Advanced Unresected Head and Neck Squamous Cell Carcinoma

Condition: Neoplasms, Head and Neck
Primary Completion Date: 2028-05-04
Phase: III
Intervention/ Treatment: DRUG: **Dostarlimab/ Placebo**

Inclusion Criteria: Participants are eligible to be included in the study only if all of the following criteria apply: Has newly diagnosed unresected LA histologically confirmed HNSCC of the oral cavity, oropharynx, hypopharynx or larynx and completed cisplatin plus radiotherapy (termed "CRT" in this protocol) with curative intent and has no evidence of distant metastatic disease. / Has provided acceptable core or excisional tissue demonstrating: / PD-L1 positive tumor status / If the primary tumor site is oropharyngeal carcinoma, the participant must have p16 IHC testing. / Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1/ Has adequate organ function.

Exclusion Criteria:

Participants are excluded from the study if any of the following criteria apply: Has received prior radiation therapy, systemic therapy, targeted therapy, or radical surgery for management of head and neck cancer not considered part of CRT. / Has cancer outside of the oropharynx, larynx, hypopharynx or oral cavity, such as nasopharyngeal, sinus, other para-nasal, or other unknown primary head and neck cancer. / Has experienced any of the following with prior immunotherapy: any irAE of Grade ≥3, immune-related severe neurologic events of any grade (e.g., myasthenic syndrome/myasthenia gravis, encephalitis, Guillain-Barré Syndrome, or transverse myelitis), exfoliative dermatitis of any grade [Stevens-Johnson Syndrome, toxic epidermal necrolysis, or DRESS (Drug Rash with Eosinophilia and Systemic Symptoms) syndrome], or myocarditis of any grade. Non-clinically significant laboratory abnormalities are not exclusionary. / Has undergone any major surgical procedure or experienced significant traumatic injury within 28 days prior to enrolment. / Has any history of interstitial lung disease or pneumonitis (past or current). / Has cirrhosis or current unstable liver biliary disease per investigator assessment defined by the presence of ascites, encephalopathy, coagulopathy, hypoalbuminemia, esophageal/gastric varices, or persistent jaundice. / Has a history or current evidence of any medical condition, therapy, or laboratory abnormality that might confound the study results, interfere with their participation for the full duration of the study intervention, or indicate it is not in the best interest of the participant to participate, in the opinion of the investigator. / Is receiving any other anticancer or experimental therapy. No other experimental therapies (including but not limited to chemotherapy, radiation, hormonal treatment, antibody therapy, immunotherapy, gene therapy, vaccine therapy, or other experimental drugs) of any kind are permitted while the participant is receiving study intervention. / Previous treatment with anti-PD-1, anti-PD-L1, or anti-PD-L2 agent or an agent directed to another stimulatory or coinhibitory T-cell receptor [e.g., Cytotoxic T-lymphocyte associated protein 4 (CTLA4), OX-40, CD137] /Is pregnant, breastfeeding, or expecting to conceive children within the projected duration of the study, starting with the Screening Visit through 120 days after the last dose of study intervention./ Has a history of severe allergic and/or anaphylactic reactions to chimeric, human or humanized antibodies, fusion proteins, or known allergies to dostarlimab or its excipients.

see Link:

clinicaltrials.gov/NCT06256588

Study Test Center	PI / SC	Phone	E-Mail
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MVZ für Onkologie und Urologie GmbH, Wilhelmshaven	Dr. med. Andrea Distelrath	04421 95600 0	

A phase 3 open-label, randomized controlled study to evaluate the efficacy and safety of Petosemtamab compared with Investigator's choice monotherapy treatment in previously treated Patients with incurable, metastatic/recurrent Head and Neck Squamous Cell Carcinoma

Condition: Head and Neck Squamous Cell Carcinoma
Primary Completion Date: 2028-02
Phase: III
Intervention/ Treatment: DRUG: **Petosemtamab/ Investigators`choice**

Inclusion Criteria:
Signed ICF before initiation of any study procedures. / Age ≥ 18 years at signing of ICF. / Histologically previously confirmed HNSCC with evidence of metastatic or locally advanced disease not amenable to standard therapy with curative intent. / HNSCC patients progressed on or after anti-PD-1 therapy and platinum-containing therapy. / The eligible HNSCC primary tumor locations are oropharynx, oral cavity, hypopharynx, and larynx. / Documentation of p16 status (positive or negative) by local laboratory IHC for patients with primary oropharyngeal cancer. / A baseline new tumor sample unless the patient has an available tumor sample as an FFPE block with sufficient material. / Measurable disease as defined by RECIST v1.1 by radiologic methods. / ECOG PS of 0 or 1 / Life expectancy ≥ 12 weeks, as per investigator / Adequate organ function (as per protocol)

Exclusion Criteria:
Central nervous system metastases that are untreated or symptomatic, or require radiation, surgery, or continued steroid therapy to control symptoms within 14 days of study entry. / Known leptomeningeal involvement / Any systemic anticancer therapy within 4 weeks of the first dose of study treatment. / Major surgery or radiotherapy within 3 weeks of the first dose of study treatment. / Persistent Grade >1 clinically significant toxicities related to prior antineoplastic therapies / History of hypersensitivity reaction to any of the excipients of treatment required for this study. / Unstable angina; history of congestive heart failure of Class II-IV New York Heart Association (NYHA) criteria, or serious cardiac arrhythmia requiring treatment or history of myocardial infarction within 6 months of study entry / History of prior malignancies with the exception of excised cervical intraepithelial neoplasia or nonmelanoma skin cancer, or curatively treated cancer deemed at low risk for recurrence with no evidence of disease / Current dyspnea at rest of any origin, or other diseases requiring continuous oxygen therapy / Current serious illness or medical conditions including, but not limited to, uncontrolled active infection, clinically significant pulmonary, metabolic or psychiatric disorders / Patients with known infectious diseases (as per protocol) / Pregnant or breastfeeding patients / Patient has a primary tumor site of nasopharynx (any histology).

see Link:

clinicaltrials.gov/NCT06496178

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

2 **„LiGeR - HN1“, MCLA-158-CL03**

Randomized, open-label phase 3 study to evaluate the efficacy and safety of petosemtamab plus pembrolizumab compared to pembrolizumab in the first-line treatment of recurrent or metastatic PD-L1+ squamous cell carcinoma of the head and neck.

Condition: Head and Neck Squamous Cell Carcinoma
Primary Completion Date: 2028-01
Phase: III
Intervention/ Treatment: DRUG: **Petosemtamab/ Pembrolizumab**

Inclusion Criteria:
Signed ICF before initiation of any study procedures / Age ≥ 18 years at signing of ICF / Histologically confirmed HNSCC with evidence of metastatic or locally recurrent disease not amenable to local therapy with curative intent. / The eligible HNSCC primary tumor locations are oropharynx, oral cavity, hypopharynx, and larynx. / HNSCC patients eligible to receive pembrolizumab as 1L monotherapy with tumors expressing PD-L1, CPS ≥1. / HNSCC patients should not have had previous systemic therapy administered in the incurable recurrent or metastatic setting / A new tumor biopsy, unless the patient has an available archival tumor sample with sufficient material / Measurable disease per Investigator assessment as defined by RECIST v1.1 by radiologic methods / ECOG Performance Status (PS) of 0-1 / Life expectancy ≥ 12 weeks, as per investigator assessment. / Left ventricular ejection fraction (LVEF) ≥50% or ≥ institutional normal limit, whichever is higher, by echocardiogram (ECHO) or multigated acquisition (MUGA) scan / Adequate organ function as defined per protocol. / HIV-positive patients are eligible only if the cluster of differentiation 4 (CD4+) count is ≥ 300/µl, viral load is undetectable, and the patient is currently receiving highly active antiretroviral therapy

Exclusion Criteria:
Central nervous system metastases that are untreated or already treated but symptomatic, or require radiation, surgery, or continued steroid therapy to control symptoms within 21 days prior to randomization / Known leptomeningeal involvement / Any systemic anticancer therapy or investigational drug within 4 weeks or 5 half-lives, whichever is shorter, before randomization / Requirement for immunosuppressive medication / Major surgery or radiotherapy within 3 weeks of randomization / Clinically significant toxicities related to prior anticancer therapies that have not returned to ≤ Grade 1 or baseline except for Grade ≤2- myalgia, neuropathy, alopecia, and any prior therapy related endocrinopathies / History of hypersensitivity reaction to any of the excipients of petosemtomab or pembrolizumab. Unstable angina; history of congestive heart failure of Class II-IV New York Heart Association (NYHA) criteria, or serious cardiac arrhythmia requiring treatment; or history of myocardial infarction within 6 months prior to randomization / History of prior malignancies within the last 5 years, with the exception of excised local cancer / Current dyspnea at rest of any origin, or other diseases requiring continuous oxygen therapy / Current serious illness or medical conditions including, but not limited to, uncontrolled active infection, clinically significant pulmonary, metabolic or psychiatric disorders / Patients with known infectious diseases as per protocol. / Pregnant or breastfeeding patients. / The patient has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy of prednisone >10 mg/day or equivalent, or any other form of immunosuppressive therapy / The patient has an active autoimmune disease that has required systemic immune suppressive treatment in the past 2 years; replacement therapy is not considered immune suppressive treatmentThe patient has had an allogeneic tissue/solid organ transplant. / Patient has a primary tumor site of nasopharynx, or sinonasal carcinoma (any histology) / Other protocol defined inclusion/exclusion criteria may apply.

see Link:

clinicaltrials.gov/NCT06525220

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Phase III, Randomized, Open-Label, Multi-Center, Global Study of Volrustomig (MEDI5752) as Sequential Therapy Versus Observation in Participants With Unresected Locally Advanced Head and Neck Squamous Cell Carcinoma, Who Have Not Progressed Following Definitive Concurrent Chemoradiotherapy

Condition: Locally Advanced Head and Neck Squamous Cell Carcinoma
Primary Completion Date: 2029-01-19
Phase: III
Intervention/ Treatment: DRUG: **Volrustomig**

Inclusion Criteria:
Histologically or cytologically documented locally advanced squamous cell carcinoma of the oropharynx, hypopharynx, oral cavity, or larynx with no evidence of metastatic disease (i.e. M0). / Confirmed unresected Stage III, Stage IVA or IVB according to the eighth edition of the American Joint Committee on Cancer (AJCC) staging manual (tumor, node, metastasis (TNM) staging system). / Participants will have completed definitive concurrent chemoradiotherapy (cCRT) with curative intent within 12 weeks prior to randomization.

Exclusion Criteria:
Histologically/cytologically confirmed head and neck cancer of any other primary anatomic location in the head and neck not specified in the inclusion criteria including participants with squamous cell carcinoma of unknown primary or non-squamous histologies (eg, nasopharynx or salivary gland). Participants with >1 primary tumors are not eligible for the study. / Participants with any of the following: Residual disease that needs further treatment with curative intent after definitive cCRT administration; / LA-HNSCC that was resected before definitive cCRT / LA-HNSCC that was treated and is recurrent at the time of screening / Participants who have received radiotherapy (RT) alone as definitive local therapy for LA-HNSCC. / Receipt of the last dose of anticancer therapy (chemotherapy and/or RT) > 12 weeks (84 days) prior to randomization.

see Link:

clinicaltrials.gov/NCT06129864

Study Test Center	PI / SC	Phone	E-Mail
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Esophageal cancer

continue...

Contact at UCC Hamburg
PD Dr. med. Marianne Sinn, Tel.: 040-7410-56882

Prospective Randomised Comparison of En Bloc Versus Piecemeal Resection of Barrett's Neoplasms of the Esophagus Neoplastic Barrett's Esophagus: Endoscopic Piecemeal vs En Bloc Resection

Condition: Barrett Esophagus/ Barrett Adenocarcinoma/ Esophagus Neoplasm
Primary Completion Date: 2025-10
Phase: N/A
Intervention/ Treatment: Procedure (**Endoscopic mucosal resection/ Endoscopic submucosal dissection**)

Inclusion Criteria:
patients to be treated for Barrett's esophagus by mucosal resection and following ablative therapy / Barrett's mucosal extension up to 10 cm maximum. / patient's ability for compliance to therapy / signed Informed Consent

Exclusion Criteria:
any lesion questionable to be resectable by mucosectomy, e.g. bulky lesions ≥10 mm in endoscopy und endosonography, suspected deep submucosal infiltration, ulcers, suspected or by FNA confirmed lymph node infiltration / Barrett's esophagus > 10 cm / lesions that would afford resection of more than 2/3rd of esophagal circumference / two or more single Barrett's lesions with bulky HGIN or early cancer histology, not to be resectable in one half of esophageal circumference / planned circumferencial resections / very serious general illness and metastatic carcinoma / coagulation disorder or anticoagulants that make biopsies and resections impossible / American Society of Anesthesiologists (ASA) status > III / pregnancy and lactation / remainders or recurrences after therapeutic history of Barrett's esophagus

see Link:

clinicaltrials.gov/NCT03427346

Study Test Center	PI / SC	Phone	E-Mail
UKE Radiology and Endoscopy	Prof. Dr. med. Thomas Rösch Tania Ruppenthal (SC)	040-7410 50098 040-7410 50089	T.Roesch@uke.de t.ruppenthal@uke.de

Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

3 „PEGASUS-1“, BUL-5/ESD

Double-blind, randomised, placebo-controlled, phase IIa trial on the efficacy and tolerability of an 8-week treatment with two different doses of budesonide orodispersible tablets vs. placebo for prevention of oesophageal strictures in adult patients after endoscopic submucosal dissection

Condition: Digestive System Diseases, esophageal SCC
Primary Completion Date: /
Phase: II
Intervention/ Treatment: DRUG: **Budesonide**

Inclusion Criteria:
patients to be treated for Barrett's esophagus by mucosal resection and following ablative therapy / Barrett's mucosal extension up to 10 cm maximum. / patient's ability for compliance to therapy / signed Informed Consent

Exclusion Criteria:
any lesion questionable to be resectable by mucosectomy, e.g. bulky lesions ≥10 mm in endoscopy und endosonography, suspected deep submucosal infiltration, ulcers, suspected or by FNA confirmed lymph node infiltration / Barrett's esophagus > 10 cm / lesions that would afford resection of more than 2/3rd of esophagal circumference / two or more single Barrett's lesions with bulky HGIN or early cancer histology, not to be resectable in one half of esophageal circumference / planned circumferencial resections / very serious general illness and metastatic carcinoma / coagulation disorder or anticoagulants that make biopsies and resections impossible / American Society of Anesthesiologists (ASA) status > III / pregnancy and lactation / remainders or recurrences after therapeutic history of Barrett's esophagus

see Link:

clinicaltrialsregister.eu/2018-002617-35

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Phase 1/2 Open-Label, Umbrella Platform Design Study of Investigational Agents in Combination With Pembrolizumab (MK-3475) With or Without Chemotherapy in Participants With 1L Locally Advanced Unresectable/Metastatic Esophageal Cancer: KEYMAKER-U06 Substudy 06E

Condition: Esophageal Squamous Cell Carcinoma
Primary Completion Date: 2032-01-04
Phase: I/II
Intervention/ Treatment: DRUG: **Leucovorin/ Levoleucovorin/ 5-Fluorouracil (5-FU)/ Oxaliplatin**_BIOLOGICAL**: Pembrolizumab/ I-DXd**

Inclusion Criteria:
Has histologically or cytologically confirmed diagnosis of locally advanced unresectable or metastatic squamous cell carcinoma of the esophagus in first-line (1L) setting. / Has measurable disease per RECIST 1.1 as assessed by the local site. investigator/radiology assessment and verified by BICR. Lesions situated in a previously irradiated area are considered measurable if progression has been shown in such lesions. / Has AEs due to previous anticancer therapies of ≤Grade 1 or baseline (except alopecia and vitiligo). Endocrine-related AEs adequately treated with hormone replacement are acceptable. / Human immunodeficiency virus (HIV)-infected participants must have well controlled HIV on antiretroviral therapy (ART). / Participants who are hepatitis B surface antigen (HBsAg) positive are eligible if they have received hepatitis B virus (HBV) antiviral therapy for at least 4 weeks, and have undetectable HBV viral load. / Participants with history of hepatitis C virus (HCV) infection are eligible if HCV viral load is undetectable. / Has Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1.
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT06780111

Study Test Center	PI / SC	Phone	E-Mail
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3 „Ideate-Esophageal01“

A Phase 3, Multicenter, Randomized, Open-label Study of Ifinatamab Deruxtecan (I-DXd) in Subjects With Pretreated Advanced or Metastatic Esophageal Squamous Cell Carcinoma (ESCC) (IDeate-Esophageal01)

Condition: Esophageal Squamous Cell Carcinoma
Primary Completion Date: 2028-06-01
Phase: III
Intervention/ Treatment: DRUG: **Ifinatamab deruxtecan/ Docetaxel/ Paclitaxel/ Irinotecan hydrochloride (HCl)**

Inclusion Criteria:
Participants aged ≥18 years (follow local regulatory requirements if the legal age of consent for study participation is >18 years old). / Has histologically or cytologically documented unresectable locally advanced or metastatic ESCC according to American Joint Committee on Cancer 8th edition staging system on ESCC. / Has disease progression post a platinum-based chemotherapy and an ICI treatment per global or local guidelines, with a maximum of 1 prior line of systemic therapy for unresectable advanced or metastatic ESCC. / The participant must provide adequate baseline tumor samples with sufficient quantity and quality of tumor tissue content as defined in the Laboratory Manual. / Has at least 1 measurable lesion on computed tomography (CT)/magnetic resonance imaging (MRI) according to RECIST v1.1 as assessed by the investigator. Measurable lesions should not be from a previously irradiated site. If the lesion at a previously irradiated site is the only selectable target lesion, a radiological assessment showing significant progression of the irradiated lesion should be provided by the investigator. / Has an ECOG PS of 0 or 1 within 7 days prior to Cycle 1 Day 1.
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT06644781

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
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Organ Preservation With Durvalumab-based Immunotherapy in Combination With Chemoradiation as Definitive Therapy for Early Stage, cT1 and cT2N0, Esophageal Adenocarcinoma With Indication for Radical Surgery: A Prospective, Multicenter Study of the FLOT-AIO Gastric Cancer Group

Condition: Esophageus Adenocarcinoma
Estimated Completion Date: 2028-12
Phase: II
Intervention/ Treatment: DRUG: **Durvalumab/ FLOT/ mFOLFOX-6_** RADIATION: **Radiotherapy**

Inclusion Criteria:
Patient has given written informed consent. / Patient is, in the investigator's judgement, willing and able to comply with the study protocol including the planned surgical treatment. / Patient is ≥ 18 years of age at time of signing the written informed consent. / Patient has been diagnosed with histologically confirmed esophageal adenocarcinoma (including gastroesophageal junction (GEJ) (Siewert I-III)) with: / cT2 N0 M0 stage or T1 N0 M0 stage and a given indication for radical surgical resection to current S3-guidelines (this includes patients with a given indication for radical surgery after endoscopic-resection of a cT1-2 N0 M0 tumor [poor grading or L1/V1 invasion or basal R1 resection or deep submucosal infiltration]) (see section 4.2.3 for detailed information). / tumor is considered medically and technically resectable. / Tumor is tested (local testing with validated assays is sufficient, e.g., Dako PD-L1 IHC 22C3 or 28-8) for PD-L1 according to combined positive score (CPS) and results must be available prior study enrollment. In addition, tumor should be tested locally for MSI status and PD-L1 according to tumor proportion score (TPS) OR a representative tumor specimen that is suitable for central determination of PD-L1 TPS and MSI status is available. The analysis requires paraffin embedded biopsy samples of the tumor to be provided to the Sponsor. / NOTE: It is encouraged that CPS, TPS and MSI testing is performed in parallel locally at the trial site prior to enrollment, but at least CPS per local testing has to be available prior to enrollment. / Patient has not received prior cytotoxic or targeted therapy. / Patient has not had a prior complete esophagogastric tumor resection. / Patient has a ECOG ≤ 1. / Patient must have life expectancy of at least 12 weeks / Female patients of childbearing potential and male patients with female partners of childbearing potential must agree to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of <1% per year during the treatment period and for at least 6 months after the last study treatment if it is in the core treatment phase or for at least 3 months after last study treatment occurred in the maintenance phase. Male patients must refrain from donating sperm during this same period. Male patients with a pregnant partner must agree to remain abstinent or to use a condom for the duration of the pregnancy. / Patient has a body weight > 30 kg / Patient has adequate hematological, hepatic and renal function as indicated by the following parameters: / Leukocytes ≥ 3,000/µL, platelets ≥ 100,000/µL without transfusion, absolute neutrophil count (ANC) ≥ 1,500/µL without granulocyte colony-stimulating factor support, hemoglobin ≥ 90 g/L (9 g/dL) - Patients may be transfused to meet this criterion. / Bilirubin ≤ 1.5 x upper limit of normal (ULN), aspartate transaminase and alanine transaminase ≤ 2.5 x ULN, alkaline phosphatase ≤ 2.5 x ULN / Serum creatinine ≤ 1.5 x ULN, or glomerular filtration rate > 45 mL/min (calculated using the Cockcroft-Gault formula) / Serum albumin ≥ 25 g/L (2.5 g/dL) / For patients not receiving therapeutic anticoagulation: INR or aPTT ≤ 1.5 x ULN; for patients receiving therapeutic anticoagulation: stable anticoagulant regimen / Patient has no human immunodeficiency virus (HIV) infection. NOTE: Patient with infection is eligible if he/she meets all the following criteria: / CD4 count is ≥350 cells/µL, viral load is undetectable, and not taking prohibited cytochrome (CYP)-interacting medications / Probable long-term survival with HIV if cancer were not present / Stable on a highly active antiretroviral therapy (HAART) regimen for ≥4 weeks and willing to adhere to their HAART regimen with minimal overlapping toxicity and drug-drug interactions with the experimental agents in this study / HIV is not multi-drug resistant / Taking medication and/or receiving antiretroviral therapy that does not interact or have overlapping toxicities with the study medication

Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT05713838

Study Test Center	PI / SC	Phone	E-Mail
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Gastric cancer and gastroesophageal junction

continue...

Contact at UCC Hamburg
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A Phase 1/2 Open-Label, Umbrella Platform Design Study of MK-2870 With Pembrolizumab (MK-3475) and Chemotherapy in Participants With 1L Locally Advanced Unresectable/Metastatic Gastroesophageal Adenocarcinoma (Gastric Adenocarcinoma, Gastroesophageal Junction Adenocarcinoma, and Esophageal Adenocarcinoma): Substudy 06C

Condition: Gastroesophageal Junction/ Gastroesophageal Adenocarcinoma/ Esophageal Neoplasms/ Esophageal Cancer
Primary Completion Date: 2027-01-17
Phase: I/II
Intervention/ Treatment: DRUG: **Capecitabine/ Leucovorin/ Levoleucovorin/ 5-FU**_BIOLOGICAL**: Pembrolizumab/ Sacituzumab Tirumotecan (sac-TMT)**

Inclusion Criteria:
Has histologically and/or cytologically confirmed diagnosis of previously untreated locally advanced unresectable or metastatic 1L gastroesophageal adenocarcinoma / Has gastroesophageal adenocarcinoma that is known to be human epidermal growth factor receptor 2 (HER2)/neu-positive are excluded. HER2 status is not required if HER2/neu testing is not mandatory per local standard of care (SOC) / Is not expected to require tumor resection during the treatment course / Has not had prior systemic therapy administered in the recurrent or metastatic setting / Has provided an archival tumor tissue sample or most recently obtained core, or incisional, or excisional biopsy for a tumor lesion / Participants who have adverse events (AEs) due to previous anticancer therapies must have recovered to <Grade 1 or baseline. Participants with endocrine-related AEs who are adequately treated with hormone replacement therapy are eligible / Has adequate organ function / Has measurable disease per Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST 1.1) as determined by the local site investigator/radiology assessment and verified by blind independent review committee (BICR) / Has Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 assessed within 3 days before allocation/randomization. / Has a life expectancy of at least 6 months / Who are Hepatitis B surface antigen (HBsAg) positive are eligible if they have received hepatitis B virus (HBV) antiviral therapy for at least 4 weeks, and have undetectable HBV viral load prior to randomization. / Who has history of hepatitis C virus (HCV) infection are eligible if HCV viral load is undetectable at screening. / Human immunodeficiency virus (HIV)-infected participants must have well-controlled HIV on antiretroviral therapy (ART)
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT06469944

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
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A Phase 1/2 Open-Label, Umbrella Platform Design Study to Evaluate the Safety and Efficacy of MK-2870 Plus Paclitaxel as the Second-Line Treatment of Participants With Advanced/Metastatic Gastroesophageal Adenocarcinoma: Substudy 06D

Condition: Gastroesophageal Junction/ Gastroesophageal Adenocarcinoma/ Esophageal Neoplasms/ Esophageal Cancer
Primary Completion Date: 2026-12-28
Phase: I/II
Intervention/ Treatment: DRUG: **Paclitaxel/ Rescue Medications**_BIOLOGICAL: **Ramucirumab/ Sacituzumab Tirumotecan**

Inclusion Criteria:
Has histologically and/or cytologically confirmed diagnosis of previously treated, 2L (received first line (1L) treatment) gastric adenocarcinoma, GEJ adenocarcinoma, or esophageal adenocarcinoma / Has metastatic disease or locally advanced, unresectable disease / Has experienced documented objective radiographic or clinical disease progression during or after 1L therapy containing any platinum/fluoropyrimidine doublet with or without immunotherapy / Participants with gastroesophageal adenocarcinoma that is known to be human epidermal growth factor receptor 2 (HER2)/neu positive are excluded. Participants with unknown HER2 status are eligible. / Has provided an archival tumor tissue sample or most recently obtained core, incisional, or excisional biopsy of a tumor lesion / AEs due to previous anticancer therapies must be ≤Grade 1 or baseline (except alopecia and vitiligo). Endocrine-related AEs adequately treated with hormone replacement are acceptable. / Has Eastern Cooperative Oncology Group performance status of 0 or 1 / Has a life expectancy of at least 3 months / Participants who are hepatitis B surface antigen (HBsAg) positive are eligible if they have received Hepatitis B Virus (HBV) antiviral therapy for at least 4 weeks, and have undetectable HBV viral load prior to randomization. / Participants with history of Hepatitis C Virus (HCV) infection are eligible if HCV viral load is undetectable at screening. / Human Immunodeficiency Virus (HIV)-infected participants must have well controlled HIV on antiretroviral therapy.

Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT06445972

Study Test Center	PI / SC	Phone	E-Mail
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NeoART - A Phase Ib/II Platform Trial Evaluating the Safety and Activity of Neoadjuvant Trastuzumab-deruxtecan Containing Combination Therapies for HER2+, Resectable Esophagogastric Adenocarcinoma

Condition: Esophagogastric Adenocarcinoma
Primary Completion Date: 2027-12-31
Phase: I/II
Intervention/ Treatment: DRUG: **Trastuzumab deruxtecan + 5FU/LV_Trastuzumab deruxtecan + FLO**

Inclusion Criteria:
Patient* has given written informed consent. / Patient is ≥ 18 years of age at time of signing the written informed consent. / Patient has histologically proven locally advanced (cT2-4, any cN, M0 OR any cT, cN+, M0 stage) gastric, esophagogastric junction or lower esophageal adenocarcinoma that: / Is considered technically resectable / Does not involve distant site of the peritoneal cavity / confirmed by diagnostic laparoscopy for all patients with tumors located in the stomach and those with type 2 and 3 GEJ adenocarcinomas according to guideline recommendation [Lordick et al. 2022]. / Type 1 GEJ and lower esophageal tumors can be enrolled without diagnostic laparoscopy (which is in line with guidelines and the current routine practice in Germany) / Patient has a HER2 positive tumor (by local testing) defined by HER2 IHC 3+ or IHC 2+ plus ISH positive with a HER2:CEP17 ratio of ≥ 2 according to classically used criteria for defining HER2 positivity [Lordick et al. 2017] . / Patient has a ECOG performance status 0 or 1. / Patient has adequate blood count, liver-enzymes, and renal function: / ANC > 1,500 cells/µL without the use of hematopoietic growth factors / Platelet count ≥ 100 x 109/L (>100,000 per mm3)** / Hemoglobin ≥ 9 g/dL** / Serum total bilirubin ≤ 1.5x institutional upper normal limit (ULN) / AST (SGOT)/ALT (SGPT) ≤ 2.5 x institutional ULN / Patients not receiving therapeutic anticoagulation must have an INR ≤ 1.5 ULN and aPTT ≤ 1.5 ULN. The use of full dose anticoagulants is allowed as long as the INR or PTT is within therapeutic limits (according to the medical standard in the institution) and the patient has been on a stable dose for anticoagulants for at least three weeks at the time of inclusion / Serum Creatinine ≤ 1.5 x ULN and a calculated creatinine clearance rate ≥ 50 mL /min / Female patients defined as women of childbearing potential (WOCBP) must agree to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of <1% per year during the treatment period and for 6 months after last dose of chemotherapy or 7 months after the last dose of T-DXd, whatever is later. / Male patients with WOCBP partners must agree to remain abstinent (refrain from heterosexual intercourse) or use barrier contraceptive during the treatment period as well as up to 4 months after last dose of T-DXd or up to 6 months after last dose of chemotherapy, whatever is later. Male patients must refrain from donating sperm during this same period.
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT06731803

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

ZANGEA - Phase II Study of Zanidatamab in Combination With Pembrolizumab and Chemotherapy in HER2 and PD-L1 Positive Metastatic Gastroesophageal Adenocarcinoma (GEA) Patients

Condition: Gastroesophageal Adenocarcinoma/ First Line Therapy/ HER2 + Gastric Cancer/ PDL-1/ Metastases
Primary Completion Date: 2029-03
Phase: II
Intervention/ Treatment: DRUG: **Zanidatamab/ Pembrolizumab/ mFOLFOX**

Inclusion Criteria:
Patient* has signed and dated a written informed consent form in accordance with regulatory and institutional guidelines and approved by an institutional Review Board / Independent Ethics Committee. This must be obtained before the performance of any protocol-related procedures that are not part of normal subject care. / Patient is, in the investigator's judgement, willing and able to comply with scheduled visits, treatment schedule, laboratory tests and other requirements of the study. / Patient is ≥ 18 years of age at time of signing the written informed consent. / Patient has been diagnosed with histologically confirmed unresectable advanced/metastatic HER2-positive (defined as IHC 3+ or IHC 2+ with ISH+) and PD-L1-positive (combined positive score CPS ≥ 1) gastroesophageal adenocarcinoma per local standard assessment of new or archival tumor tissue. Results of local HER2 and PD-L1 assessment will be retrospectively confirmed by central pathological re-assessment. / Note: In case of metachronous metastases, particularly in case of prior treatment with PD-(L)1-antibodies, a fresh re-biopsy should be performed for immunohistochemistry testing (local pathology), if feasible. / Patient has assessable disease (measurable or non-measurable) per RECIST v1.1. / Patient did not receive previous palliative treatment. Prior adjuvant or neoadjuvant chemotherapy, immunotherapy, radiotherapy and/or chemoradiotherapy (but not anti HER2-targeted treatment) are permitted as long as the last administration of the last regimen (whichever was given last) occurred at least 6 months prior to enrolment. / Patient has ECOG performance status ≤ 1. / Patient has adequate hepatic, renal and hematologic functions: / Absolute number of neutrophils (ANC) ≥ 1.5 x 10^9/L / Platelets ≥ 100x10^3/µL / Serum creatinine ≤ 1.5 x ULN or creatinine clearance (measured by 24 h urine) ≥ 30 mL/min (i.e., if serum creatinine level is > 1.5 x upper limit of normal (ULN), then a 24-hour urine test must be performed to check the creatinine clearance to be determined. / AST (SGOT) and ALT (SGPT) ≤ 3.0 x ULN (or ≤ 5.0 x ULN if liver metastases are present) / Total Bilirubin ≤ 1.5 x ULN (or < 3.0 x ULN in case of prior liver involvement or Gilbert's Syndrome) / Patient has adequate coagulation function as defined by International Normalized Ratio (INR) ≤ 1.5, and a partial thromboplastin time (PTT) ≤ 5 seconds above the ULN (unless receiving anticoagulation therapy). / Women of childbearing potential (WOCBP) must have a negative serum or urine pregnancy test (minimum sensitivity 25 IU/L or equivalent units of human chorionic gonadotrophin [hCG]) within 7 days prior to the start of study drug. Women must not be breastfeeding. WOCBP must use a highly effective method(s) of contraception during the treatment period and for 4 months after last dose of zanidatamab and/or pembrolizumab, or 6 months after the last dose of chemotherapy, whichever occurs last. Males who are sexually active with WOCBP must agree to remain abstinent or follow instructions for method(s) of contraception during the treatment and for 4 months after the last dose of zanidatamab and/or pembrolizumab, or 6 months after the last dose of chemotherapy, whichever occurs last. In addition, male subjects must be willing to refrain from sperm donation during this time. / There are no data that indicate special gender distribution. Therefore, patients will be enrolled in the study gender-independently.

Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT07176312

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A Phase 3, Multicenter, Open-label, Randomized Study to Compare the Efficacy and Safety of MK-2870 Versus Treatment of Physician's Choice in 3L+ Advanced/Metastatic Gastroesophageal Adenocarcinoma (Gastric Adenocarcinoma, Gastroesophageal Junction Adenocarcinoma, and Esophageal Adenocarcinoma)

Condition: Gastroesophageal cancer
Primary Completion Date: 2027-01-04
Phase: III
Intervention/ Treatment: Drug: **Trifluridine-Tipiracil/ Irinotecan/ Paclitaxel/ Docetaxel/ Rescue medication/ Supportive care measures**_Biological: **Sacituzumab tirumotecan**

Inclusion Criteria:
Has a histologically-or cytologically-confirmed diagnosis of advanced, unresectable or metastatic gastric adenocarcinoma, gastroesophageal junction adenocarcinoma, or esophageal adenocarcinoma / Has measurable disease per Response Evaluation Criteria in Solid Tumors 1.1 (RECIST 1.1) as assessed by the local site investigator/radiology. Lesions situated in a previously-irradiated area are considered measurable if progression has been shown in such lesions. / Has received, and progressed on, at least 2 prior chemotherapy and/or immunotherapy regimens for advanced, unresectable or metastatic gastroesophageal adenocarcinoma. / Participants are eligible regardless of human epidermal growth factor receptor-2 (HER2) status. Participants who are HER2+ must have previously received trastuzumab where available/appropriate / Has adequate organ function / Has provided tumor tissue sample for determination of trophoblast cell-surface antigen 2 (TROP2) status by the central laboratory before randomization for stratification / Participants who have AEs due to previous anticancer therapies must have recovered to Grade ≤1 or baseline (except for alopecia and vitiligo). Participants with endocrine related AEs who are adequately treated with hormone replacement therapy are eligible / Has measurable disease per Response Evaluation Criteria In Solid Tumors (RECIST) 1.1 as assessed by the local site investigator/radiology / Has Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 within 3 days before randomization / Has ability to swallow oral medication for those who may receive trifluridine-tipiracil / Human immunodeficiency virus (HIV) infected participants must have well-controlled HIV on antiretroviral therapy (ART) / Hepatitis B surface antigen (HBsAg) positive participants are eligible if they have received hepatitis B virus (HBV) antiviral therapy and have undetectable HBV viral load / Participants with a history of hepatitis C virus (HCV) infection are eligible if HCV viral load is undetectable
Exclusion criteria:
see Link:

clinicaltrials.gov/NCT06356311

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4 „ARTEMIDE-Gastric-01“

A Randomized, Phase Ⅲ Study of Rilvegostomig in Combination With Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First Line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Condition: HER2-positive Gastric CancerGastroesophageal Junction Adenocarcinoma
Primary Completion Date: 2029-04-27
Phase: III
Intervention/ Treatment: Drug: **Rilvegostomig/ Trastuzumab deruxtecan/ Trastuzumab/ Pembrolizumab/ 5-fluorouracil/ Capecitabine/ Cisplatin/ Oxaliplatin**

Inclusion Criteria:
HER2 positive for gastric cancer on a tumor biopsy. / PD-L1 combined positive score (CPS) ≥ 1. / Provision of tumor tissue sample from recent biopsy adequate for HER2 and PD-L1 testing. / Previously untreated, unresectable, locally advanced or metastatic gastric or GEJ adenocarcinoma. / WHO or Eastern Cooperative Oncology Group performance status of 0 or 1. / Have measurable target disease assessed by the Investigator based on RECIST v1.1. / Have adequate organ and bone marrow function within 14 days before randomization. / LVEF ≥ 55% within 28 days before randomization. / Adequate treatment washout period before randomization.

Exclusion criteria:
Lack of physiological integrity of the upper gastrointestinal tract. / Known dihydropyrimidine dehydrogenase enzyme deficiency. / Contraindication to pembrolizumab or trastuzumab, contraindications to fluoropyrimidine (5-FU and capecitabine) or platinum (cisplatin and oxaliplatin) treatment as per local label. / History of another primary malignancy except for malignancy treated with curative intent with no known active disease within 3 years before the first dose of study intervention and of low potential risk for recurrence. / Persistent toxicities caused by previous anti-cancer therapy. / Spinal cord compression or brain metastases unless asymptomatic, treated and stable and not requiring corticosteroid or anticonvulsant may be included in the study if they have recovered from the acute toxic effect of radiotherapy. / Uncontrolled infection including tuberculosis and active hepatitis A infection. / Uncontrolled infection requiring intravenous (IV) antibiotics, anti-virals, or antifungals. / Recent receipt of live, attenuated vaccine. / Chronic/active HBV or HCV infection unless controlled. / Clinically significant cardiac or psychological conditions. / Active or prior documented autoimmune or inflammatory disorders requiring chronic treatment with steroids or other immunosuppressive treatment. / History of (non-infectious) ILD/pneumonitis, has current ILD/pneumonitis, or where suspected ILD/pneumonitis cannot be ruled out by imaging at screening. / Lung-specific intercurrent clinically significant illnesses. / Any active non-infectious skin disease requiring systemic treatment. / A pleural effusion, ascites or pericardial effusion that requires drainage, peritoneal shunt, or cell-free and concentrated ascites reinfusion therapy (CART). / History of any of the following: drug-induced severe cutaneous adverse reaction. / Any concurrent antic-ancer treatment with the exception of receptor activator of nuclear factor kappa-B ligand inhibitors. / Have had major surgical procedure recently (excluding placement of vascular access) or recent significant traumatic injury or an anticipated need for major surgery during the study. / Current or prior use of immunosuppressive medication within 14 days before study intervention.
see Link:

clinicaltrials.gov/NCT06764875

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Surgical treatment for adenocarcinoma of the gastroesophageal junction (AEG type II): transthoracic esophagectomy vs. transhiatal extended gastrectomy.

Condition: Malignant neoplasm of the stomach
Primary Completion Date: N/A
Phase: IV
Intervention/ Treatment: Arm 1: **Transthoracic esophagectomy with gastric pull-up**_Arm 2: **Transhiatal extended gastrectomy**

Inclusion Criteria:
Gender: All / Histologically proven adenocarcinoma AEG type II / Non-metastatic tumor, resectable by both transthoracic esophagectomy and transhiatal extended gastrectomy according to the local surgeon / Age ≥ 18 - ECOG Eastern Cooperative Oncology Group (ECOG) 0-2 / ASA < 4. / Pre-therapeutic tumor stage cT1-4a N0/N+, M0 / In the case of stage cT4a, curative resectability must be explicitly verified by the local surgeon prior to randomization. / Patients with locally advanced tumors (T3-T4 or N+) who have received four cycles of chemotherapy (FLOT) preoperatively / Negative serum pregnancy test during the screening period for women of childbearing age / Patients with a history of cardiac disease should receive a cardiology consultation and have a left ventricular ejection fraction > 50% (determined by echocardiography). / Adequate pulmonary function (pulmonary function tests only required in symptomatic patients) with FEV1>/= 1.5 l/s / Adequate bone marrow function (white blood cells > 3x10^9 /l; hemoglobin > 9 g/dl; platelets > 100x10^9 /L), renal function (glomerular filtration rate >60 mL/min), and hepatic function (total bilirubin < 1.5x upper limit of normal (ULN), aspartate transaminase (AST) < 2.5x ULN, and alanine transaminase (ALT) < 3x ULN) / Written informed consent
Exclusion criteria:
Squamous cell carcinomas, adenosquamous carcinomas, or other non-adenocarcinomas / Advanced, inoperable, or metastatic AEG type II tumor / AEG type II in stage cT4b or M+ / AEG type II cT4a that has been assessed by the local surgeon as not being curatively resectable / Histologically proven AEG type I or III - Severe tumor stenosis preventing endoscopic tumor classification according to Siewert / Tumors extending more than 5 cm proximal to the Z-line / Tumor resectable only by transthoracic esophagectomy or only by transhiatal extended gastrectomy / Lymph node metastases resectable only by transthoracic esophagectomy (e.g., in the middle of the upper mediastinum) or only by transhiatal extended gastrectomy / Patients with locally advanced tumors (T3-T4 or N+) who have not received preoperative chemotherapy (FLOT) or who have received more or less than the permitted 4 cycles of chemotherapy / Clinically significant (active) cardiac disease (e.g., symptomatic coronary heart disease or myocardial infarction within the last 12 months) / Clinically significant pulmonary disease (forced expiratory volume in one second (FEV1) < 1.5 L/s) / Pregnant and breastfeeding women / Individuals who are in any way dependent on the principal investigator or employed by the sponsor or principal investigator. / Individuals who are legally incompetent / Individuals who are institutionalized
see Link:

Drks.de: DRKS00016923

Study Test Center	PI / SC	Phone	Wenke
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Universitätsklinikum Hamburg-Eppendorf

A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants With HER2-expressing Gastric cancer

Condition: Gastric cancer
Primary Completion Date: 2026-07-30
Phase: I/II
Intervention/ Treatment: Drug: **Fluorouracil (5-FU)/ Capecitabine/ Biological: Durvalumab/ Oxaliplatin/ Trastuzumab/ Trastuzumab deruxtecan/ Cisplatin/**
Biological: **Pembrolizumab/ Volrustomig/ Rilvegostomig**

Inclusion Criteria:
Male and female participants must be at least 18 years of age. Other age restrictions may apply as per local regulations. / **Disease Characteristics:** Locally advanced, unresectable, or metastatic disease based on most recent imaging. / For Part 1, 2, 3a, 4a pathologically documented adenocarcinoma of the stomach/GEJ/esophagus, HER2-low (IHC 2+/ISH-negative or IHC 1+)adenocarcinoma of the stomach/GEJ/esophagus, HER2-positive (IHC 3+ or IHC 2+/ISH+) based on local tissue testing results. / For Part 3b and 4b, pathologically documented based on local tissue testing results. / For Part 1, progression on or after at least one prior trastuzumabcontaining regimen For Part 2, Part 3 and Part 4, previously untreated for unresectable or metastatic adenocarcinoma of the stomach/GEJ/ esophagus with with HER2-positive (Part 2 and Part 3 [Arm 3A] and Part 4 [Arm 4A]) or HER2-low (Part 3 [Arm 3B] and Part 4 [Arm 4B])) status. / Has measurable target disease assessed by the Investigator based on RECIST version 1.1. / Has protocol defined adequate bone marrow and organ function including cardiac, renal and hepatic function. / If of reproductive potential, agrees to use a highly effective form of contraception or avoid intercourse during and upon completion of the study.
Exclusion criteria: History of active primary immunodeficiency, known HIV, active chronic, or past hepatitis B infection, or hepatitis C infection. / Uncontrolled intercurrent illness. / History of non-infectious pneumonitis/ILD, current ILD, or where suspected ILD that cannot be ruled out by imaging at screening. / Lung-specific intercurrent clinically significant severe illnesses. / Uncontrolled infection requiring intravenous (IV) antibiotics, antivirals, or antifungals. / Pleural effusion, ascites or pericardial effusion that requires drainage, peritoneal shunt, or Cell-free and Concentrated Ascites Reinfusion Therapy (CART). / Has spinal cord compression or clinically active central nervous system metastases.
see Link:

clinicaltrials.gov/NCT04379596

Study Test Center	PI / SC	Phone	E-Mail
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4 „PREVENT“, HIPEC/FLOT9

Preventive HIPEC in Combination With Perioperative FLOT Versus FLOT Alone for Resectable Diffuse Type Gastric and GastrEsophageal Junction Type II/III Adenocarcinoma

Condition: Gastric cancer, Gastroesophageal Junction Adenocarcinoma
Primary Completion Date: 2026-11-01
Phase: III
Intervention/ Treatment: DRUG: **5-Fluorouracil/ Leucovorin/ Oxaliplatin/ Docetaxel/ Cisplatin**

Inclusion Criteria:
Histologically confirmed, medically operable, resectable diffuse or mixed type (according to Lauren's classification) adenocarcinoma of the gastrEsophageal junction (AEG II-III) or the stomach (uT3, uT4a, any N category, M0), or any T N+ M0 patient / Patient has received 3 to 6 cycles of neoadjuvant FLOT (de-escalation or dose modification allowed) / No preceding cytotoxic or targeted therapy other than neoadjuvant FLOT (including de-escalated or dose reduced schema) therapy / No prior partial or complete tumor resection / Female and male patient ≥ 18 and ≤ 75 years. Female patient with childbearing potential needs to have a negative pregnancy test within 7 days prior to study start. Males and females of reproductive potential must agree to practice highly effective contraceptive measures* during the study. Male patients must also agree to refrain from father a child during treatment and additionally to use a condom during treatment period. Their female partner of childbearing potential must also agree to use an adequate contraceptive measure. *highly effective (i.e. failure rate of <1% per year when used consistently and correctly) methods: intravaginal and transdermal combined (estrogen and progestogen containing) hormonal contraception; injectable and implantable progestogen-only hormonal contraception; intrauterine device (IUD); intrauterine hormone-releasing system (IUS); bilateral tubal occlusion; vasectomised partner; sexual abstinence (complete abstinence is defined as refraining from heterosexual intercourse during the entire period of risk associated with the study treatments). / ECOG ≤ 1 / Exclusion of distant metastases by CT or MRI of abdomen, pelvis, and thorax, bone scan or MRI (if bone metastases are suspected due to clinical signs). Exclusion of the infiltration of any adjacent organs or structures by CT or MRI / Laparoscopic exclusion of peritoneal carcinomatosis at initial staging, before start of FLOT chemotherapy / Hematological, hepatic and renal function parameters adequate to allow surgical procedure and HIPEC at investigator´s discretion / Patient able and willing to provide written informed consent and to comply with the study protocol and with the planned surgical procedures

Exclusion criteria:
Patient without neoadjuvant therapy or those who received a neoadjuvant therapy other than FLOT / Known hypersensitivity against 5-FU, leucovorin, oxaliplatin, or docetaxel / Other known contraindications against, 5-FU, leucovorin, oxaliplatin, or docetaxel / Clinically significant active coronary heart disease, cardiomyopathy or congestive heart failure, NYHA III-IV / Clinically significant valvular defect / Past or current history of other malignancies not curatively treated and without evidence of disease for more than 3 years, except for curatively treated basal cell carcinoma of the skin and in situ carcinoma of the cervix / Criteria of primary unresectability, e.g.:Radiologically documented evidence of major blood vessel invasion or invasion of adjacent organs (T4b). **Or** Patients with involved retroperitoneal (e.g. para-aortal, paracaval or interaortocaval lymph nodes) or mesenterial lymph nodes (distant metastases!) / Other severe internal disease or acute infection / Patient has undergone major surgery within 28 days prior to enrollment / Cirrhosis at a level of Child-Pugh B (or worse) or cirrhosis (any degree) and a history of hepatic encephalopathy or ascites. / On-treatment participation in another interventional clinical study in the period 30 days prior to inclusion and during the study / Patient pregnant or breast feeding, or planning to become pregnant / Patient in a closed institution according to an authority or court decision (AMG § 40, Abs. 1 No. 4) / Any other concurrent antineoplastic treatment including irradiation / Known intraabdominal adhesion situs / Pre-existing peritoneal seeding

see Link:

clinicaltrials.gov/NCT04

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Universitäres Cancer Center HAMBURG
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Minimally invasive versus open Gastrectomy. A multicenter randomized controlled trial.

Condition: Malignant neoplasm of stomach
Estimated Completion Date: /
Phase: N/A
Intervention/ Treatment: PROCEDURE: Minimally invasive vs open gastrectomy

Inclusion Criteria:
Sex: All / Minimum Age: 18-84 Years / Additional Inclusion Criteria: Planned total gastrectomy after first diagnosis of gastric cancer / Ability of patient to understand character and individual consequences of the clinical trial / Written informed consent

Exclusion criteria:
ECOG performance status > 2 / Planned extended gastrectomy or less than total gastrectomy (e.g. adenocarcinoma of esophagogastric junction (AEG) I and AEG II, distal gastric tumors of intestinal subtype) / Previous gastric surgery or extensive adhesions seriously complicating MIG / Other active oncologic disease or history of cancer limiting prognosis in comparison to the gastric cancer / Emergency setting / Language problems rendering patient unable to fill out patient reported outcome questionnaires / Participation in another intervention-trial with interference of intervention and/or outcome of this trial / Pregnancy
Exclusion criteria previously or during staging laparoscopy: T4 / M1

see Link:

Drks.de/DRKS00025765

Study Test Center	PI / SC	Phone	Wenke
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4 „CLARITY Gastric 01“

A multicenter, open-label, sponsor-blinded, randomized, phase III study of AZD0901 monotherapy versus investigator's choice therapy in adult participants with advanced/metastatic adenocarcinoma of the stomach or gastroesophageal junction expressing claudin18.2, second or third line

Condition: Gastric Cancer, Gastroesophageal Junction Cancer
Estimated Completion Date: 2026-04-10
Phase: III
Intervention/ Treatment: DRUG: **AZD0901/ Ramucirumab+ paclitaxel/ Paclitaxel/ Docetaxel/ Irinotecan/ TAS-102/ Apatinib**

Inclusion Criteria:
Capable of giving signed informed consent prior to any study procedure. / Participant must be at least 18 years or the legal age of consent in the jurisdiction in which the study is taking place at the time of signing the ICF. / Histologically confirmed unresectable, locally advanced or metastatic adenocarcinoma of gastric, GEJ, or distal esophagus (distal third of the esophagus) and the following requirement: Participants with positive CLDN18.2 expression from archival tumor collected within past 24 months or from a fresh biopsy. / Disease progression on or after at least one prior line of treatment (LoT) for advanced or metastatic disease, which included a fluoropyrimidine and a platinum, for advanced or metastatic disease. / Must have at least one measurable or evaluable lesion assessed by the Investigator based on RECIST 1.1. / ECOG performance status of 0 or 1 with no deterioration over the previous 2 weeks prior to baseline or day of first dosing. / Predicted life expectancy of ≥ 12 weeks. / Adequate organ and bone marrow function / Body weight of ≥ 35 kg. / Sex and Contraceptive Requirements

Exclusion Criteria:
Participants with known HER2 positive status as defined as IHC 3+ or IHC 2+/ISH + (Cases with HER2: CEP17 ratio ≥ 2 or an average HER2 copy number ≥ 6.0 signals/cell are considered positive by ISH). Participants must undergo local (or have had) HER2 testing by IHC/ISH, and the most recent result of HER2 status will be used to determine the eligibility. / Participant has significant or unstable gastric bleeding and/or untreated gastric ulcers. / CNS metastases or CNS pathology including: epilepsy, seizures, aphasia, or stroke within 3 months prior to consent, severe brain injury, dementia, Parkinson's disease, neurodegenerative diseases, cerebellar disease, severe uncontrolled mental illness, psychosis, CNS involvement of autoimmune diseases. / Participant has known clinically significant corneal disease (eg, active keratitis or corneal ulcerations). / Persistent toxicities (CTCAE Grade ≥ 2) caused by previous anticancer therapy, excluding alopecia. Participants with irreversible toxicity that is not reasonably expected to be exacerbated by study intervention may be included (eg, hearing loss). / Prior exposure to any ADC with MMAE payload or any CLDN18.2 targeting treatment other than naked monoclonal antibody (eg, CLDN18.2 targeting CAR-T cell therapy, multi-specific antibody including targeting CLDN18.2, etc).
see Link:

clinicaltrials.gov/NCT06346392

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4 „Destiny-Gastric05“

A Multicenter, Randomized, Open-Label, Phase 3 Trial of Trastuzumab Deruxtecan (Enhertu®) Plus Chemotherapy Plus or Minus Pembrolizumab Versus Chemotherapy Plus Trastuzumab Plus or Minus Pembrolizumab as First-Line Treatment in Participants With Unresectable, Locally Advanced or Metastatic HER2-Positive Gastric Or Gastroesophageal Junction (GEJ) Cancer (Destiny-Gastric05) expressing claudin18.2, second or third line

Condition: Gastric Cancer, Gastroesophageal Junction Cancer
Estimated Completion Date: 2028-06-01
Phase: III
Intervention/ Treatment: DRUG: **Trastuzumab Deruxtecan/ Pembrolizumab/ Trastuzumab/ Chemotherapy**

Inclusion Criteria:
Sign and date the Tissue Prescreening ICF, prior to HER2 and PD-L1 CPS central testing. Sign and date the Main Screening ICF, prior to the start of any trial-specific qualification procedures. Sign and date the Optional PGx ICF (included in the Main Screening ICF) prior to any PGx procedure. / Adults ≥18 years of age on the day of signing the ICF. Follow local regulatory requirements if the legal age of consent for trial participation is >18 years old. / Previously untreated, unresectable, locally advanced or metastatic gastric or GEJ adenocarcinoma histologically confirmed by pathology report. Prior treatment in the perioperative and/or adjuvant setting is permissible, provided there is >6 months between the end of perioperative or neoadjuvant treatment and the diagnosis of recurrent disease. / Note: Prior use of IO (ie, anti-PD-1/PD-L1) therapy in the (neo)adjuvant setting is allowed as long as there is >6 months between the end of IO therapy and the diagnosis of recurrent disease. / Centrally determined HER2-positive (IHC 3+ or IHC 2+/ISH-positive) gastric or GEJ cancer as classified by the American Society of Clinical Oncology-College of American Pathologists for GC on a tumor biopsy as detected by prospective central test on new (core, incisional, excisional biopsy) or existing tumor tissue taken at the time of diagnosis of locally advanced or metastatic disease. / Note: Archival samples taken from a previous diagnostic or surgical biopsy not previously irradiated can be accepted. Details pertaining to tumor tissue submission can be found in the Study Laboratory Manual. / All participants must provide a tumor sample for tissue-based IHC staining to centrally determine HER2 expression, PD-L1 CPS, and other correlatives. The mandatory FFPE tumor sample can be from either the primary tumor or metastatic biopsy. Specimens with limited tumor content (as centrally determined) and cytology samples are inadequate for defining tumor HER2 and PD-L1 status. / At least 1 target measurable lesion on CT or MRI, assessed by the investigator based on RECIST v1.1. Lesions situated in a previously irradiated area are considered measurable if progression has been shown in such lesions. / LVEF ≥50% within 28 days before randomization.
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT06731478

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Pancreatic cancer

continue...

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Conventional partial pancreatoduodenectomy versus extended pancreatoduodenectomy (TRIANGLE procedure) for pancreatic head cancer – the randomized controlled TRIANGLE study

Condition: pancreatic head carcinoma
Estimated Completion Date: /
Phase: N/A
Intervention/ Treatment: SURGICAL: **Triangle – compared to standard Whipple surgery**

Inclusion Criteria:
Preoperative inclusion criteria: Patients with suspected resectable, borderline, or locally advanced pancreatic head cancer (i.e., ductal adenocarcinoma of the pancreas, IPMN carcinoma (intraductal papillary mucinous neoplasms), or periampullary carcinoma of the pancreatobiliary type) / Patients scheduled for elective partial pancreatoduodenectomy (regardless of neoadjuvant therapy) / Presumed resectability according to the surgical protocol for the experimental and control interventions as assessed by the treating surgeon / Ability of the patient to understand the nature and individual consequences of the clinical trial / Informed written consent / Age ≥18 years
Intraoperative inclusion criteria (prior to randomization): No distant metastases / No para-aortic lymph node metastases / Intraoperative confirmation that the patient can be operated on using both surgical methods (experimental or control group)
Exclusion criteria:
Participation in another interventional study that could influence the intervention and outcome of this study / ASA (American Society of Anesthesiologists) grade > 3 / Distant metastases
see Link:

drks.de/DRKS00030576

Study Test Center	PI / SC	Phone	E-Mail
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Conventional partial pancreatoduodenectomy versus extended pancreatoduodenectomy (TRIANGLE procedure) for pancreatic head cancer – the randomized controlled TRIANGLE study

Condition: Pancreatic Ductal Adenocarcinoma
Estimated Completion Date: 2031-09-01
Phase: III
Intervention/ Treatment: DRUG: **Oxaliplatin/ Irinotecan/ Folinic acid/ 5-fluorouracil/ Gemcitabine/ Capecitabine**

Inclusion Criteria:
Histologically proven pancreatic ductal adenocarcinoma including variants, and pancreatic acinar cell carcinoma. / Patient had provided tumour tissue at resection for RNAseq. / Macroscopically complete resection (R0 or R1 resection). / Female and male Patients aged from 18 to 79 years. / WHO performance status 0-1. / No prior radiotherapy and no previous chemotherapy for pancreatic cancer. / Full recovery from surgery and patient able to receive chemotherapy: adequate oral nutrition of ≥ 1500 calories per day and free of significant nausea and vomiting. / Adequate hematologic function: Absolute neutrophil count ≥ 1,500 cells/mm3, platelets ≥ 100,000 cells/mm3 and haemoglobin ≥ 8 g/L (transfusion permitted). / Serum total bilirubin ≤ 1.5 times the institutional upper limit of normal. / Creatinine clearance ≥ 50 mL/min. / Patient of child-bearing potential (for female patient: study entry after a menstrual period and a negative pregnancy test) must agree to use highly effective methods of contraception during the study and for 6 months after the last study treatment for women and 6 months for men. / Intended interval since surgery between 21 and 84 days at date of randomization. / Public or private health insurance cover. / Ability of subject to understand character and individual consequences of the clinical trial. / Not legally incapacitated. / Written informed consent.
Exclusion criteria:
Solid pseudopapillary neoplasm, neuroendocrine neoplasm, pancreatoblastoma, bile duct cancer, and ampullary cancer. / Distant metastases, including ascites or malignant pleural effusion. / Macroscopic incomplete tumour removal (R2 resection). / Post-operative CA 19-9 > 180 U / ml before randomization on study. / Cardiomyopathy or congestive heart failure, NYHA III-IV or coronary heart disease symptoms. / Major comorbidity that may preclude the delivery of treatment or known active infection (HIV or untreated chronic hepatitis B or active hepatitis C) or uncontrolled diabetes. / Pre-existing neuropathy, Gilbert's disease or known genotype UGT1A1*28 /*28. / Inflammatory disease of the colon or rectum, or intestinal obstruction, or severe postoperative uncontrolled diarrhoea. / Known severe dihydropyrimidine dehydrogenase (DPD) deficiency (activity score <1). There are clear guidelines for dose reductions for patients with a score of 1 and 1,5 (2 is normal activity) / Pregnancy and lactation. / Participation in other clinical trials or observation period of competing trials, respectively. / History of hypersensitivity or other known contraindication to the investigational medicinal product or to any drug with similar chemical structure or to any excipient present in the pharmaceutical form of the investigational medicinal product. / Past or current history of other malignancies not curatively treated and without evidence of disease for more than 5 years, except for curatively treated basal cell carcinoma of the skin and in situ carcinoma of the cervix or bladder, or low/intermediate risk prostate cancer (Gleason score ≤7) with normal PSA levels. / Any other concurrent antineoplastic treatment including irradiation
see Link:

clinicaltrials.gov/NCT05314998

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Distal pancreatectomy – a randomized controlled trial comparing minimally invasive resection with open resection (DISPACT-2)

Condition: Malignant neoplasm of the pancreas
Estimated Completion Date: N/A
Phase: N/A
Intervention/ Treatment: Arm 1: **Minimally invasive distal pancreatectomy_Arm 2: Open distal pancreatectomy**

Inclusion Criteria:
Gender: All / Planned distal pancreatectomy with or without splenectomy for any indication / Age ≥ 18 years / Ability to understand the nature and individual consequences of the clinical trial / Written informed consent

Exclusion criteria:
Patients scheduled for pancreatic resection other than distal pancreatectomy / Distant metastases or tumor infiltration of the superior mesenteric vein, superior mesenteric artery, or hepatic artery- Infiltration of adjacent organs / CA 19-9 > 1000 IU/mL / ASA > 3 - Previous major open abdominal surgery / Participation in another interventional study with interference with the intervention and outcome of this study- Lack of compliance and lack of written informed consent
see Link:

Drks.de: DRKS00014011

Study Test Center	PI / SC	Phone	E-Mail
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5 „RAMPS-Study“

Radical antegrade modular pancreatectomy (RAMPS) compared to conventional distal pancreatectomy for malignant pancreatic tumors – The multicenter, randomized, controlled RAMPS study

Condition: Malignant neoplasm of the pancreas
Estimated Completion Date: N/A
Phase: N/A
Intervention/ Treatment: Arm 1: **Radical antegrade modular pancreatectomy (RAMPS)**_Arm 2: **Standard distal pancreatectomy**

Inclusion Criteria:
Gender: all Indication for open or minimally invasive distal pancreatectomy / Resectable malignancy of the pancreatic body or tail / Age ≥ 18 years - American Society of Anesthesiologists (ASA) classification ≤ III / Ability to understand the nature and individual consequences of the intervention and control groups, which are equally possible, written informed consent

Exclusion criteria:
Preoperative: Distant metastases,tumor infiltration of several neighboring organs or visceral arteries (except the splenic artery), T4 stage (according to the 8th edition of the American Joint Committee on Cancer staging system), surgical indication for secondary malignancies/metastases infiltrating the pancreas, Participation in another interventional study that interferes with the intervention/outcome of this study / **Intraoperative** : Intraoperative detection of distant metastases - Technical unresectability
see Link:

Drks.de: DRKS00033031

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Radical antegrade modular pancreatectomy (RAMPS) compared to conventional distal pancreatectomy for malignant pancreatic tumors – The multicenter, randomized, controlled RAMPS study

Condition: Malignant neoplasm of the pancreas
Estimated Completion Date: N/A
Phase: N/A
Intervention/ Treatment: Arm 1: **Radical antegrade modular pancreatectomy (RAMPS)**_Arm 2: **Standard distal pancreatectomy**

Inclusion Criteria:
Gender: all Indication for open or minimally invasive distal pancreatectomy / Resectable malignancy of the pancreatic body or tail / Age ≥ 18 years - American Society of Anesthesiologists (ASA) classification ≤ III / Ability to understand the nature and individual consequences of the intervention and control groups, which are equally possible, written informed consent

Exclusion criteria:
Preoperative: Distant metastases,tumor infiltration of several neighboring organs or visceral arteries (except the splenic artery), T4 stage (according to the 8th edition of the American Joint Committee on Cancer staging system), surgical indication for secondary malignancies/metastases infiltrating the pancreas, Participation in another interventional study that interferes with the intervention/outcome of this study / **Intraoperative** : Intraoperative detection of distant metastases - Technical unresectability
see Link:

Drks.de: DRKS00033031

Study Test Center	PI / SC	Phone	E-Mail
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Effect of an additional brown foot point anastomosis in patients after pancreatic head resection

Condition: pancreatic head resection
Estimated Completion Date: /
Phase: III
Intervention/ Treatment: brown foot point anastomosis

Inclusion Criteria:
Patients with benign or malignant diseases of the pancreas, distal bile duct and duodenum requiring pylorus-preserving pancreaticoduodenectomy / surgical reconstruction by Child reconstruction, defined as pancreaticojejunostomy followed by hepaticojejunostomy followed by duodenojejunostomy / 3age ≥ 18 years. / ability to understand the nature and individual consequences of the study and to sign the informed consent form.
Exclusion criteria:
patients undergoing a classic Kausch-Whipple resection / patients undergoing pylorus-preserving pancreaticoduodenectomy requiring intraoperative arterial resection / patients undergoing pylorus-preserving pancreaticoduodenectomy requiring multivisceral resections / laparoscopic or laparoscopic-assisted pancreatic surgery / distal pancreatectomy / enucleations / patients with a history of previous major GI surgery/ 8. pregnant or breastfeeding women/ 9. planned relaparotomy up to 30 days after the initial operation/ Emergency surgery
see Link:

https://drks.de/DRKS00024364

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Robot-assisted versus open pancreatoduodenectomy in patients with primarily resectable pancreatic head cancer (DIPLOMA-2×2): An international, multicenter, randomized, controlled, roll-over trial with blinded patients and reviewers

Condition: Extrahepatic bile duct
Primary Completion Date: 2028-12-31
Phase:
Intervention/ Treatment: PROCEDURE: **Robot-assisted pancreatoduodenectomy/Open pancreatoduodenectomy**

Inclusion Criteria:
18 years or older / Indication for elective pancreatoduodenectomy / Primary resectable malignant disease of the pancreas or distal bile duct / Both open and robotic surgery technically possible / Fit for surgery(Neoadjuvant therapy is possible if the tumor is initially resectable)

Exclusion Criteria:
Non-malignant tumor in the head of the pancreas / History of chronic pancreatitis / Lymph node or distant metastases / Vascular contact / Additional resection of a second tumor required during the same procedure / Pregnancy / BMI >35 kg/m2 / Participation in another study with an effect on the outcome
see Link:

Dpcg.nl: NL77750.018.21

Study Test Center	PI / SC	Phone	E-Mail
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A Phase II, Open-Label, Multicenter, Randomized Study of the Efficacy and Safety of Adjuvant Autogene Cevumeran Plus Atezolizumab and mFOLFIRINOX Versus mFOLFIRINOX Alone in Patients With Resected Pancreatic Ductal Adenocarcinoma

Condition: Adenocarcinoma, Pancreatic Ductal
Estimated Completion Date: 2029-12-27
Phase: II
Intervention/ Treatment: DRUG: **Autogene cevumeran/ Atezolizumab/ mFOLFIRINOX**

Inclusion Criteria:
Histologically confirmed diagnosis of PDAC / Pancreatic cancer tumor, lymph node, metastasis (TNM) pathological staging values of T1-T3, N0-N2, and M0 per the American Joint Committee on Cancer (AJCC) Cancer Staging Manual / Macroscopically complete (R0 or R1) resection of PDAC / Unequivocal absence of disease after surgery as assessed by the investigator within 28 days prior to randomization / CA19-9 level measured within 14 days prior to initiation of study treatment / Interval of between 6 and 12 weeks since resection of PDAC / Full recovery from surgery and ability to receive atezolizumab, autogene cevumeran, and mFOLFIRINOX in the investigator's judgment / Adequate hematologic and end-organ function / Female participants of childbearing potential must be willing to avoid pregnancy during the treatment period and for 28 days after the final dose of autogene cevumeran, for 9 months after the last dose of chemotherapy, and for 5 months after the final dose of atezolizumab. They must refrain from donating eggs for 9 months after the last dose of chemotherapy. / Male participants with a female partner of childbearing potential or pregnant female partner must remain abstinent or use specified contraceptive methods during the treatment period and for 28 days after the final dose of autogene cevumeran and for 6 months after the last dose of chemotherapy. Men must refrain from donating sperm during this same period.

Exclusion Criteria:
Prior adjuvant, neoadjuvant, or induction treatment for pancreatic cancer / Plan for further adjuvant anti-cancer therapy for PDAC (e.g., radiotherapy and/or chemotherapy), not mandated per protocol, to be initiated after completion of mFOLFIRINOX treatment / Absence of spleen; distal pancreatectomy with splenectomy is exclusionary / Preexisting Grade >/=2 neuropathy / Known complete dihydropyrimidine dehydrogenase (DPD) deficiency including homozygous or compound heterozygous mutations of DPYD genetic locus associated with DPD deficiency / Disorders of the colon or rectum, or postoperative complication leading to Grade >/=2 diarrhea / Pregnancy or breastfeeding / Active or history of autoimmune disease or immune deficiency / Treatment with brivudine, sorivudine, or their chemically-related analogues, which are inhibitors of DPD, within 4 weeks prior to initiation of study treatment / Current or planned treatment with strong inhibitors or inducers of cytochrome P450 3A4 (CYP3A4) and/or uridine diphosphate glucoronosyltransferase 1A1 (UGT1A1).

see Link:

clinicaltrials.gov/NCT05968326

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
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A Randomized, Phase 2/3 Study Comparing BMS-986504 in Combination With Nab-paclitaxel and Gemcitabine Versus Placebo in Combination With Nab-paclitaxel and Gemcitabine in Participants With Untreated Metastatic Pancreatic Ductal Adenocarcinoma Harboring Homozygous MTAP Deletion

Condition: Pancreatic Ductal Adenocarcinoma
Estimated Completion Date: 2029-05-03
Phase: II/III
Intervention/ Treatment: DRUG: **BMS-986504/ Gemcitabine/ Nab-paclitaxel/ Placebo**

Inclusion Criteria:
Histologically or cytologically confirmed diagnosis of metastatic pancreatic ductal adenocarcinoma (PDAC). / Evidence of homozygous methylthioadenosine phosphorylase (MTAP) deletion or MTAP loss detected in tumor tissue. / Metastatic disease with at least 1 measurable lesion as per Response Evaluation Criteria in Solid Tumors version v1.1 (RECIST v1.1). / Participants must not have received any systemic anticancer treatments in the metastatic setting. / If clinically indicated and as per investigator discretion, participants may receive up to 1 cycle of Nab-paclitaxel/Gemcitabine (nab-p/gem) in the metastatic setting and must have not progressed or required discontinuation due to intolerable toxicity. / Initial cycle of nab-p/gem administered in the metastatic setting must have been completed prior to randomization.
Exclusion Criteria:
Concurrent malignancy (present during screening) requiring treatment or history of prior malignancy active within 2 years prior to screening. / Other protocol-defined Inclusion/Exclusion criteria apply.
see Link:

clinicaltrials.gov/NCT07076121

Study Test Center	PI / SC	Phone	E-Mail
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Universitätsklinikum Hamburg-Eppendorf

Cholangiocellular carcinoma

continue...

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An Open-label Randomized Trial of the Efficacy and Safety of Zanidatamab With Standard-of-care Therapy Against Standard-of-care Therapy Alone for Advanced HER2-positive Biliary Tract Cancer

Condition: Biliary Tract Cancer
Primary Completion Date: 2028-12-01
Phase: III
Intervention/ Treatment: DRUG: **Zanidatamab/ Cisplatin/ Gemcitabine/ Pembrolizumab/ Durvalumab**

Inclusion Criteria:
Histologically- or cytologically-confirmed Biliary Tract Cancer (BTC), including Gallbladder Cancer (GBC), Intrahepatic Cholangiocarcinoma (ICC), or Extrahepatic Cholangiocarcinoma (ECC). / Locally advanced unresectable or metastatic BTC and not eligible for curative resection, transplantation, or ablative therapies. / Received no more than 2 cycles of systemic therapy which is limited to Cisplatin and Gemcitabine (CisGem) with or without a PD-1/L1 inhibitor (physician's choice of durvalumab or pembrolizumab, where approved under local regulations) for advanced unresectable or metastatic disease. / HER2-positive disease (defined as IHC 3+; or IHC 2+/ ISH+) by IHC and in situ Hybridization (ISH) assay (in participants with IHC 2+ tumors) at a central laboratory on new biopsy tissue or archival tissue from the most recent biopsy. / Assessable (measurable or non-measurable) disease as defined by Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST 1.1), per investigator assessment. / Male or female ≥ 18 years or age (or the legal age of adulthood per country-specific regulations). / Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. / Adequate organ function / Females of childbearing potential must have a negative pregnancy test result. / Females of childbearing potential and males with a partner of childbearing potential must be willing to use 2 methods of birth control.

Exclusion criteria:
Prior treatment with a HER2-targeted agent / Prior treatment with checkpoint inhibitors, other than durvalumab or pembrolizumab / The following BTC histologic subtypes are excluded: small cell cancer, neuroendocrine tumors, lymphoma, sarcoma, mixed tumor histology, and mucinous cystic neoplasms detected in the biliary tract region. / Use of systemic corticosteroids. / Brain metastases / Severe chronic or active infections / History of allogeneic organ transplantation. / Active or prior autoimmune inflammatory conditions / History of interstitial lung disease or non-infectious pneumonitis. / Participation in another clinical trial with an investigational medicinal product within the last 3 months. / Females who are breastfeeding / Any other medical, social, or psychosocial factors that, in the opinion of the investigator, could impact safety or compliance with study procedures. / Use of phenytoin

see Link:

clinicaltrials.gov/NCT06282575

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
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6 „pro-duct002“

A prospective, multicentre, non-randomised, unblinded, single-arm study evaluating patients with perihilar cholangiocarcinoma (Bismuth corlette type III / IV) classified as non-resectable for liver transplantation. This study was designed as a prospective pilot study to collect data on the oncological value of liver transplantation for patients with perihilar cholangiocarcinoma

Condition: Extrahepatic bile duct
Primary Completion Date: 31.12.2028
Phase: II
Intervention/ Treatment: PROCEDURE: **Liver transplantation**

Inclusion Criteria:
Gender: All / Minimum age: 18 years / Maximum age: 70 years / Protocol-defined diagnosis of perihilar cholangiocarcinoma in patients with primary sclerosing cholangitis (PSC): i.e. histological diagnosis of cholangiocarcinoma (obtained by endoscopic retrograde cholangiography [ERC]) or dominant stenosis plus cytological diagnosis of severe dysplasia or two consecutive cytological results of severe dysplasia or carcinoma, with the second result obtained after 2 weeks of antibiotic treatment to exclude inflammatory changes / - Protocol-defined diagnosis of perihilar cholangiocarcinoma in patients without PSC: clinical diagnosis of proximal cholangiocarcinoma based on ERC plus a second method (CT or MRI), cytological material is obtained during ERC, but cytological evidence of carcinoma or severe dysplasia is not mandatory / Tumour not curatively resectable as assessed by an experienced hepatobiliary surgeon (> 50 liver resections for perihilar cholangiocarcinoma) / Online review of the defined patient data and acceptance for priority listing by a Eurotransplant expert panel consisting of two experts recruited from the Eurotransplant Liver Allocation Committee; / in case of a non-unanimous decision, involvement of a third expert for a final decision on the priority list with a corresponding matchMELD / Mandatory staging laparoscopy (including robot-assisted) / laparotomy prior to prioritisation (see SOP staging laparoscopy 7.5.1.4) / Age between 18 and 70 years / negative pregnancy test / written consent prior to study inclusion (all other procedures are routine clinical procedures in the treatment of these patients)
Exclusion Criteria:
locally very advanced, non-resectable tumour with infiltration of adjacent organs and the main trunk of the hepatic artery / - a visible tumour mass on CT or MRI scan with a diameter of more than 3 cm / significantly elevated CA 19-9 level (> 1000 U / ml) / - Decompression of the bile ducts by external drainage (PTCD) / - tumors suspicious for gallbladder cancer / - Known lymph node or distal metastases (determined by CT scan and laparoscopy (including robot-assisted) / laparotomy, for further investigations, if deemed necessary, a PET scan is recommended) / - Patients undergoing multi-organ / transplantation or who have previously undergone solid organ or bone marrow transplantation / - previous photodynamic therapy, radiotherapy, brachytherapy or combinations of these procedures / previous tumour biopsy (except via ERC), systematic lymphadenectomy (except SOP-defined staging laparoscopy/laparotomy), surgical dissection in the area of the hepatoduodenal ligament (except cholecystectomy for other reasons) or previous completed or attempted surgery for hilar cholangiocarcinoma / Pregnancy or breastfeeding / Patients who are not willing to consent to the storage and dissemination of pseudonymised medical data for study purposes / General contraindications for liver transplantation / Prisoners, persons detained by the courts or authorities
see Link:

drks.de:DRKS00013276

Study Test Center	PI / SC	Phone	E-Mail
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Phase 2 Study of Preoperative Gemcitabine Plus Cisplatin with Durvalumab (MEDI4736) and Tremelimumab in intrahepatic cholangiocarcinoma

Condition: Intrahepatic cholangiocarcinoma
Primary Completion Date: /
Phase: II
Intervention/ Treatment: DRUG: **Durvalumab/ Tremelimumab/ Gemcitabine/ Cisplatin**

Inclusion Criteria:
Must have a life expectancy of at least 12 weeks. / Ability of patient to understand nature, importance and individual consequences of clinical trial. / Sufficient language skills to comprehend verbal and written information and capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol. / Age >18 years. / Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0 or 1. / 6. At least 1 lesion, not previously treated, that qualifies as a RECIST 1.1 target lesion (TL) at baseline. Tumor assessment by computed tomography (CT) scan or magnetic resonance imaging (MRI) must be performed within 28 days prior to treatment start / Histologically confirmed diagnosis of iCCA and available tumor tissue for translational research. / Technical resectability of the primary tumor. / No prior systemic or local therapy and no prior partial or complete tumor resection for iCCA. / Body weight >30 kg / Adequate normal organ and marrow function as defined below: **a.** Absolute neutrophil count (ANC ≥1.5 × 109 /L), **b.** Hemoglobin ≥9 g/dL (transfusion permitted within 30 days of study entry). **c.** Platelet count ≥100 × 109/L **d.** Serum bilirubin ≤2.0 x institutional upper limit of normal (ULN). **e.** Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) ≤3x ULN **f.** Creatinine normal for age: if serum creatinine is abnormal for age the patient must have a calculated creatinine clearance ≥50 mL/min using the CKD-EPI formula. **g.** Quick ≥70% or International normalized ratio (INR) ≤ 1.2 x ULN / Women post-menopausal for more than two years can participate in the trial. Women with childbearing potential can only participate, if they are surgically sterile or a negative pregnancy test (serum) is available within 7 days before trial and they are willing to either be totally sexually abstinent OR practice at least one highly effective and medically accepted contraception method during trial (see chapter 7.1). They should have been stable on their chosen method of birth control for a minimum of 3 months before entering the study and continue to use it throughout the total duration of the drug treatment and the drug washout period (180 days after the last dose of durvalumab + tremelimumab and Gemcitabine/Cisplatin combination therapy). / Men must agree to remain abstinent or use contraceptive measures, and agree to refrain from donating sperm, as defined: With female partners of childbearing potential or pregnant female partners, men must remain abstinent or use a condom plus an additional contraceptive method that together result in a failure rate of 1% per year during the treatment period and for at least 180 days after the last dose of study treatment to avoid exposing the embryo. Vasectomised males are considered fertile and should still use a male condom plus spermicide as indicated above during the clinical study.
see Link:

Clinialtrialsregister.eu:2021-004411-11

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
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Radiofrequency Ablation Via Catheter and Transpapillary Access in Patients With Cholangiocarcinoma

Condition: Cholangiocarcinoma, Klatskin Tumor, Bile Duct Cancer, Liver Cancer
Primary Completion Date: 2026-01
Phase: N/A
Intervention/ Treatment: PROCEDURE: **Intraductal biliary radiofrequency ablation**

Inclusion Criteria:
Unresectable perihilar and/or ductal CCA with bile duct stenting and palliative systemic therapy as indicated by the local Multidisciplinary Team (MDT) / Written informed consent
Eastern Cooperative Oncology Group (ECOG) performance status 0-1 / Age ≥18 years / Eligibility for palliative systemic therapy based on clinical and laboratory parameters (except hyperbilirubinemia) as determined by the local MDT / No prior radiofrequency ablation (RFA) for CCA / No repeated bile duct stenting in the past 3 months (trial inclusion is possible upon first stent replacement or initial stent placement within past 3 months) / No concomitant disease or malignancy interfering with the study procedure or efficacy outcome measures, particularly no severe or uncontrolled cardiovascular disease (congestive heart failure NYHA III or IV, unstable angina pectoris, myocardial infarction within ≤3 months, significant arrhythmias) and no psychiatric disorders precluding understanding of information of trial related topics and giving informed consent
see Link:

Clinicaltrials.gov:NCT06175845

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Universitäres Cancer Center HAMBURG
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Efficacy and Safety of GemCis Plus Trastuzumab Plus Pembrolizumab in Previously Untreated HER2-positive Biliary Tract Cancer

Condition: Biliary Tract Cancer/ HER2 Gene Mutation/ HER2
Primary Completion Date: 2026-07
Phase: II
Intervention/ Treatment: Drug: **SOC plus trastuzumab and pembrolizumab**

Inclusion Criteria:
Participant provides written informed consent. / Male/female Participants who are at least 18 years of age on the day of signing informed consent. / Participant is, in the investigator's judgement, willing and able to comply with the study protocol. / Participant has histologically confirmed diagnosis of cholangiocarcinoma or gallbladder cancer. / Participant is not eligible for surgery. / Participants must have HER2-positive disease defined as either IHC 3+ or IHC 2+, the latter in combination with FISH+, as assessed locally on primary tumor OR positively confirmed by NGS-analysis OR positively confirmed by mRNA / Participant has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1. Evaluation of ECOG is to be performed within 7 days prior to the first dose of study intervention. / Male Participants must agree to use a contraception as detailed in Appendix 3 of this protocol during the treatment period and for at least 7 months after the last dose of study treatment and refrain from donating sperm during this period. / Female Participants are eligible to participate if they are not pregnant (see Appendix 3), not breastfeeding, and at least one of the following conditions applies: / Not a woman of childbearing potential (WOCBP) as defined in Appendix 3 OR / A WOCBP who agrees to follow the contraceptive guidance as given in Appendix 3 during the treatment period and for at least 7 months after the last dose of study intervention / Participant has measurable disease based on RECIST v1.1. Lesions situated in a previously irradiated area are considered measurable if progression has been demonstrated in such lesions. / Have adequate organ function as defined in the following table (Table 2). / Criteria for known Hepatitis B and C positive subjects Hepatitis B and C screening tests are not required unless there is a known history of HBV or HCV infection and/or as mandated by local health authority / Hepatitis B positive subjects / Participants who are HBsAg positive are eligible if they have received HBV antiviral therapy for at least 4 weeks and have undetectable HBV viral load (< 100 IU/mL) prior to enrollment / Participants should remain on anti-viral therapy throughout study intervention and follow local guidelines for HBV anti-viral therapy post completion of study intervention. / Participants with history of HCV infection are eligible if HCV viral load is undetectable at screening. / Participants must have completed curative anti-viral therapy at least 4 weeks prior to enrollment.
see Link:

Clinicaltrials.gov:NCT06178445

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Small bowel cancer

continue...

Contact at UCC Hamburg
PD Dr. med. Marianne Sinn, Tel.: 040-7410-56882

7 „coldAPC“

The objective of this study is to investigate the feasibility for the treatment of precancerous peri-ampullary FAP polyps in the duodenum using low-thermal argonplasma.

Condition: Adenomatous Polyposis Coli, Familial Adenomatous Polyposis, Duodenal Adenoma
Primary Completion Date: 2025-01-30
Phase: N/A
Intervention/ Treatment: DEVICE: **low energy argonplasma coagulation**

Inclusion Criteria:
confirmed FAP disease / duodenal polyposis with recommendation of a follow-up EGD in 12 months corresponding to stage III (7-8 points) according to Spigelman / presence of duodenal polyps < 10 mm written Informed Consent

Exclusion Criteria:
resence of lesions that are suspicious of the presence of high-grade dysplasia or carcinoma / pregnancy or breastfeeding / severe general illnesses (permanent ASA (American Society of Anesthesiologists) III and IV) who do not prognostically benefit from follow-up, life expectancy < 1 year / severe coagulopathy / any visible state of duodenal surface that makes APC treatment impossible, e.g. inflammation, stricture, stenosis or scarring changes/scar areas
see Link:

clinicaltrials.gov/NCT06435533

Study Test Center	PI / SC	Phone	E-Mail
UKE Radiology and Endoscopy	Prof. Dr. med. Thomas Rösch Tania Ruppenthal (SC)	040-7410 50098 040-7410 50089	T.Roesch@uke.de t.ruppenthal@uke.de

Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Effectiveness of supplementation of a probiotic (OMNi-BiOTiC 10) together with individual nutritional counselling with a focus on a prebiotic diet compared to individual nutritional counselling with a focus on a prebiotic diet alone for improving gastrointestinal symptoms in colorectal cancer survivors - A prospective double-blind randomised placebo-controlled intervention study

Condition: Duodenum
Primary Completion Date: /
Phase: N/A
Intervention/ Treatment: PROCEDURE: **Cold snare removal/ Hot snare resection**

Inclusion Criteria:
All genders, age ≥ 18 years / Non-ampullary, sporadic duodenal adenomas with a size between 20 and 50 mm in longitudinal diameter or up to a maximum of 2/3 of the circumference (longitudinal extension max. 5 cm). The diameter is measured with an open loop of known size.

Exclusion Criteria:
Recurrent adenomas or adenomas after previous intervention / Existing pregnancy / ASA > III / Tumour disease without curative therapy option / Coagulation disorders/patients under dual antiplatelet therapy Lesions that are macroscopically suspicious of an existing submucosal invasion / Patients who cannot be informed

see Link:

drks.de/DRKS00029731

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
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Colorectal carcinoma/ colon

continue...

Contact at UCC Hamburg
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Soft coagulation of the resection margin using Schlingenspitzen vs. no coagulation after large-area cold loop resection – a randomized controlled trial

Condition: Benign neoplasm: colon, unspecified
Primary Completion Date: N/A
Phase: N/A
Intervention/ Treatment: Cold snare WITH marginal coagulation, Cold snare WITHout marginal coagulation

Inclusion Criteria:
Gender: All / Minimum age: 18 years / Non-previously treated, non-pedunculated laterally spreading tumor (LST) of the granular type (homogeneous or non-granular) ≥ 20 mm in the colon or rectum, willingness and ability to participate in the follow-up study, provision of information and a signed informed consent form.

Exclusion Criteria:
Morphologically confirmed sessile serrated lesion or LST nodular-mixed type, macroscopically probable or suspected or histologically proven carcinoma, polyp >5 cm maximum diameter, patient unable to give consent, pregnancy, known blood clotting disorder, anticoagulant therapy that cannot be paused with double (in favor of a single) antiplatelet agent, an adenosine diphosphate receptor antagonist, direct oral anticoagulant therapy, Marcumar or heparin therapy, presence of chronic inflammatory bowel disease, inadequate bowel preparation, ASA score IV-V.***see Link:***

drks.de:DRKS00035688

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
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A Multi-site, Open-label, Phase II, Randomized, Controlled Trial to Compare the Efficacy of RO7198457 Versus Watchful Waiting in Resected, Stage II (High Risk) and Stage III Colorectal Cancer Patients Who Are ctDNA Positive Following Resection

Condition: Colorectal Cancer Stage II & III
Primary Completion Date: 2026-11
Phase: II
Intervention/ Treatment: DRUG: **RO7198457 intravenous (IV)**, OTHER: **Observational group (no intervention)**

Inclusion Criteria:
Patients must be a man or woman of at least 18 years of age. / Patients must have Stage II/Stage III rectal cancer or Stage II (high risk)/Stage III colon cancer per American Joint Committee on Cancer (AJCC) 2017 that has been surgically totally resected (R0 confirmed by pathology report). Stage II (high risk) colon cancer is defined as Stage II disease with any of the following risk factors for recurrence: / T4 / Grade ≥ 3. / Clinical presentation with bowel obstruction or perforation. / Histological signs of vascular, lymphatic or perineural invasion. / < 12 nodes evaluated after surgery. / For the CLM Cohort: patients must have metastatic colorectal cancer (mCRC) (Stage IV) with resected CLM (synchronous and metachronous CLM within 6 months of initial diagnosis) per AJCC 2017, after standard of care (SoC) primary resection and curative-intent hepatectomy (R0 confirmed by pathology report) with or without (neo-)adjuvant chemotherapy (prior to hepatectomy), and planned adjuvant chemotherapy. / For the Biomarker Cohort: patients with tumors of the colon, including but not limited to, colon adenocarcinoma, carcinoid tumors (including goblet cell carcinoid/adenocarcinoma), and tumors of the appendix, whose tumors were surgically resected and are planned for adjuvant chemotherapy (per institutional standards), can be included. / Patients must have detectable ctDNA prior to start of adjuvant chemotherapy (AdCTx) (except for the Biomarker Cohort). / ctDNA assay must be performed through this trial or study BNT000-001 ctDNA screening protocol. / Patients must have an Eastern Cooperative Oncology Group Performance Status of 0-1. / Patients must have adequate hematologic, bone marrow and organ function as defined by the protocol. / Adequate tumor material in formalin-fixed paraffin embedded blocks or as sectioned tissue (only upon approval by sponsor) must be available (as described in the laboratory manual). For the CLM Cohort: tumor material must come from primary resection for patients who undergo staged approach, or from available archival material from the previously untreated tumor biopsy from the primary. / At least 5 tumor neoantigens identified in the provided tumor sample. / The patient has started a standard of care AdCTx preferably within 8 weeks but no later than 10 weeks post-surgery and has completed at least 3 months of treatment of a 3- or a 6-month course of chemotherapy (including rest days). For the CLM Cohort: patient must have completed AdCTx with or without (neo-)adjuvant chemotherapy for up to 6 months in total or total intended amount determined by care providers per SoC. AdCTx must have started preferably within 8 weeks, but no later than 10 weeks, after hepatectomy. For the Biomarker Cohort: patient must have received at least one cycle of adjuvant chemotherapy per institutional standards.
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT04486378

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Forced postoperative mobilization and biotracking after colorectal oncological resections

Condition: Colorectal Cancer
Primary Completion Date: N/A
Phase: N/A
Intervention/ Treatment: Intervention: **mobilization program**

Inclusion Criteria:
Gender: All / Minimum age: 18 years / Patients with planned (elective) minimally invasive bowel or rectal surgery due to CRC / No multivisceral resection with planned resection of other organs (exceptions are small atypical liver wedge resections, biopsies, abdominal wall resection, partial prostate/bladder resection, adnexectomy, cholecystectomy) / Mobilization according to the planned program is physically and mentally possible (e.g. no pre-existing bedridden or wheelchair-bound patients). e.g. no pre-existing bedridden or wheelchair-bound condition) / No contraindication to wearing activity tracker watches
Exclusion Criteria:
Primary open surgical technique
see Link:

drks.de:DRKS00033443

Study Test Center	PI / SC	Phone	E-Mail
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A Phase 3, Randomized, Open-label, Multicenter Clinical Study to Evaluate the Safety and Efficacy of MK-1084, Cetuximab, and mFOLFOX6 Versus mFOLFOX6 With or Without Bevacizumab as First-line Treatment of Participants With KRAS G12C-mutant, Locally Advanced Unresectable or Metastatic Colorectal Cancer (KANDLELIT-012)

Condition: Colon Adenocarcinoma, Rectal Adenocarcinoma
Primary Completion Date: 2029-08-27
Phase: III
Intervention/ Treatment: DRUG: **MK-1084/ Oxaliplatin/ Leucovorin/levofolinate calcium/ 5-Fluorouracil/ Bevacizumab**_BIOLOGICAL: **Cetuximab**

Inclusion Criteria:
Has a histologically confirmed diagnosis of locally advanced unresectable or metastatic (unresectable Stage III or Stage IV as defined by American Joint Committee on Cancer [AJCC] eighth edition) colorectal adenocarcinoma / Part 2 only: Has not received systemic anticancer therapy for locally advanced unresectable or metastatic colorectal cancer / Tumor tissue demonstrates presence of a Kirsten rat sarcoma viral oncogene homolog G12C (KRAS G12C) mutation / Human immunodeficiency virus (HIV)-infected participants must have well controlled HIV on antiretroviral therapy (ART) / Participants who are Hepatitis B surface antigen (HBsAg) positive are eligible if they have received hepatitis B virus (HBV) antiviral therapy and have undetectable HBV viral load / Participants with history of hepatitis C virus (HCV) infection are eligible if HCV viral load is undetectable

Exclusion Criteria:
Has active inflammatory bowel disease requiring immunosuppressive medication or previous clear history of inflammatory bowel disease (eg, Crohn's disease, ulcerative colitis, chronic diarrhea) / Has uncontrolled, significant cardiovascular disease or cerebrovascular disease / Has known dihydropyrimidine dehydrogenase (DPD) deficiency / HIV-infected participants with a history of Kaposi's sarcoma and/or Multicentric Castleman's Disease / Has received prior systemic anticancer therapy including investigational agents within 4 weeks before randomization / Has 1 or more conditions that, in the opinion of the investigator, make the participant ineligible for treatment with bevacizumab / Has known additional malignancy that is progressing or has required active treatment within the past 3 years / Has known active central nervous system (CNS) metastases and/or carcinomatous meningitis or leptomeningeal disease / Has active infection requiring systemic therapy / Has not adequately recovered from major surgery or have ongoing surgical complications / Has a history of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease
see Link:

clinicaltrials.gov/NCT06997497

Study Test Center	PI / SC	Phone	E-Mail
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Phase 3 Multicenter, Randomized, Open-label, Active-controlled Study of Sotorasib, Panitumumab and FOLFIRI Versus FOLFIRI With or Without Bevacizumab-awwb for Treatment-naïve Subjects With Metastatic Colorectal Cancer With KRAS p.G12C Mutation (CodeBreaK 301)

Condition: Metastatic Colorectal Cancer
Primary Completion Date: 2028-01-31
Phase: III
Intervention/ Treatment: DRUG: **FOLFIRI Regimen/ Sotorasib/ Panitumumab/ Bevacizumab-awwb**

Inclusion Criteria:
Pathologically documented metastatic colorectal adenocarcinoma with KRAS p.G12C mutation by a locally validated assay. / Central laboratory detection of KRAS p.G12C mutation. / Measurable metastatic disease per RECIST v1.1 criteria. / Eastern Cooperative Oncology Group (ECOG) Performance Status of ≤ 1. / Adequate organ function.

Exclusion Criteria:
•. Active, untreated brain metastases. / Leptomeningeal disease / Previous treatment with a KRAS p.G12C inhibitor / History of interstitial pneumonitis or pulmonary fibrosis or evidence of interstitial pneumonitis or pulmonary fibrosis on baseline CT scan

see Link:

clinicaltrials.gov/NCT06252649

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG

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A Randomized Phase II Trial Evaluating Fruquintinib in Combination With Tislelizumab in Microsatellite Stable / Proficient Mismatch Repair (MSS/pMMR) Metastatic Colorectal Cancer Without Active Liver Metastases

Condition: Metastatic Colorectal Cancer
Primary Completion Date: 2029-12-31
Phase: II
Intervention/ Treatment: DRUG: **Fruquintinib/ Tislelizumab/ Trifluridine/tipiracil/ Bevacizumab**

Inclusion Criteria:
Patient* provide signed informed consent form. / Patient is ≥ 18 years at the time of given informed consent. / Patient has been diagnosed with histologically or cytologically proven microsatellite stable (MSS)/proficient mismatch repair (pMMR) metastatic adenocarcinoma of the colon or rectum, which is not amenable to potentially curative resection. / Known RAS (KRAS or NRAS) and BRAF V600E mutational status. Note: These mutations are mutually exclusive. Therefore, if one of the factors is mutated, it is not required to determine the mutation status of the others, as they are then assumed to be wildtype. / Patient without liver metastases (NLM) defined as subjects without active liver metastases at screening as determined on baseline imaging of the liver as performed by CT scan with contrast or MRI. Definitively treated liver metastases (which includes surgical resection, microwave or radiofrequency ablation, or stereotactic body radiation therapy, but not yttrium-90 or chemoembolization alone) that were treated at least 3 months prior to enrollment with no evidence of radiologic progression on subsequent imaging are considered to be non-active liver metastases.
1.Patient received at least one line of previous treatment with a fluoropyrimidine, oxaliplatin, irinotecan, VEGF(R) and if indicated EGFR and/or BRAF inhibitors in the advanced setting, or the patient has been intolerable or ineligible to those treatments. / Patient has an ECOG performance status ≤ 1. / Patient has a life expectancy > 16 weeks. / Patient has adequate hematological, hepatic and renal function. / Absolute number of neutrophils (ANC) ≥ 1.5 x 109/L_Platelets ≥ 100 x 109/L_Total bilirubin ≤ 1.5 times the upper limit of normal (ULN) (or < 2 x ULN in case of prior liver involvement or Gilbert's disease)_AST (SGOT) and ALT (SGPT) ≤ 2.5 x ULN, AP ≤ 5 x ULN_Serum creatinine ≤ 1.5 x ULN or creatinine clearance (measured by 24 h urine) ≥ 30 mL/min (i.e., if serum creatinine level is > 1.5 x ULN, then a 24-hour urine test must be performed to check the creatinine clearance to be determined)._Urinary protein ≤2+ on dipstick or routine urinalysis (UA; if urine dipstick or routine analysis is ≥3+, a 24-hour urine collection for protein must demonstrate <2000 mg of protein in 24 hours to allow participation in this protocol) / Adequate coagulation function as defined by International Normalized Ratio (INR) ≤ 1.5, and a partial thromboplastin time (PTT) ≤ 5 seconds above the ULN (unless receiving anticoagulation therapy). / Female patients of childbearing potential or male patients in Arm B with female partners of childbearing potential must agree to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of <1% per year during the treatment period and for at least 6 months after the last trial treatment. Male patients in Arm B with a pregnant partner must agree to remain abstinent or to use a condom for the duration of the pregnancy. Female patients of child-bearing potential must have a negative pregnancy test within the last 7 days prior to the start of trial therapy. / Patient is willing and able to comply with the protocol (including contraceptive measures) for the duration of the study including undergoing treatment and scheduled visits and examinations including follow up. / There are no data that indicate special gender distribution. Therefore, patients will be enrolled in the trial gender-independently.
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT06856837

Study Test Center	PI / SC	Phone	E-Mail
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Preoperative FOLFOX Versus Postoperative Risk-adapted Chemotherapy in Patients With Locally Advanced Rectal Cancer and Low Risk for Local Failure: A Randomized Phase III Trial of the German Rectal Cancer Study Group

Condition: Metastatic Rectal Cancer
Primary Completion Date: 2030-08
Phase: III
Intervention/ Treatment: DRUG: **mFOLFOX (neoadjuvant)/ XELOX (neoadjuvant)/ mFOLFOX (adjuvant)/ XELOX (adjuvant)/ Capecitabine (adjuvant)/ infusional 5-FU/FA "AIO" regimen (adjuvant)/ infusional 5-FU/FA "de Gramont" (adjuvant)**

Inclusion Criteria:
Male and female patients with histologically confirmed diagnosis of rectal adenocarcinoma localised 0 - 16 cm from the anocutaneous line as measured by rigid rectoscopy (i.e. lower, middle and upper third of the rectum), depending on MRI-defined inclusion criteria (see below). / Staging requirements: High-resolution magnetic resonance imaging (MRI) of the pelvis is the mandatory local staging procedure. / Transrectal endoscopic ultrasound (EUS) is used to help discriminate between T1/2 and early T3 tumors. / **MRI-defined inclusion criteria:** Lower third (0-6 cm): cT1/2 with clear cN+ based on MRI-criteria (see SOP in chapter 13.3 of the appendix), provided CRM- and EMVI- (defined as MRI-EMVI score 0-3; see SOP in chapter 13.3 of the appendix) / Middle third (≥ 6-12 cm): cT1/2 with clear cN+ provided CRM- and EMVI-; cT3a/b, i.e. evidence of extramural tumor spread into the mesorectal fat of ≤ 5 mm provided N-, CRM-, and EMVI- / Upper third (≥ 12-16 cm): cT1/2 with clear cN+ provided CRM- and EMVI-; any cT3-4 irrespective of nodal status. / Spiral-CT of the abdomen and chest to exclude distant metastases. / Aged at least 18 years. No upper age limit. / WHO/ECOG Performance Status ≤1. / **Adequate haematological, hepatic, renal and metabolic function parameters:** / Leukocytes ≥ 3.000/mm³, ANC ≥ 2.000/mm³, platelets ≥ 100.000/mm³, Hb > 9 g/dl / Serum creatinine ≤ 1.5 x upper limit of normal / Bilirubin ≤ 2.0 mg/dl, SGOT-SGPT, and AP ≤ 3 x upper limit of normal. / QTc interval (Bazett**) ≤ 440 ms / Informed consent of the patient.
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT04495088

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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

deCOMpression of stoma and two-stage elective resection vs. emergency resection in patients with left-sided obstructive colon cancer

Condition: Malignant neoplasm of the colon
Primary Completion Date: N/A
Phase: N/A
Intervention/ Treatment: INTERVENTION: **Arm 1:Creation of a decompressive stoma, followed by a two-stage elective oncological resection after convalescence**
Arm 2:Emergency resection of the left-sided obstructive colon tumor

Inclusion Criteria:
Gender: All / Minimum age: 18 years / Maximum age: no maximum age / Colon obstruction in patients with left-sided colon or upper rectal tumors (splenic flexure to intraperitoneal rectum (tumor > 12 cm from the anal margin)) who are being treated with curative intent_ / The tumor must be highly suspicious for colorectal cancer on CT or endoscopy / Evidence of colonic dilatation by computed tomography / The tumor, including possible metastases, must be considered curatively resectable / Patient's ability to give consent
Exclusion Criteria:
Right-sided colon _- Extraperitoneal rectal carcinoma of the lower and middle third (tumor < 12 cm from the anal margin) _- Life expectancy < 120 days due to advanced tumor disease _- Locally advanced tumor disease with local infiltration of other structures, which excludes R0 resection or requires neoadjuvant treatment - Patients being treated for palliative purposes_- Signs of intestinal perforation on CT (free air) _- Patients who are not eligible for surgery (ASA score ≥ IV) _- Failure to comply with requirements_- Addictions or other conditions that prevent the affected person from assessing the nature and scope of the clinical trial and its possible consequences
see Link:

Drks.de: DRKS00031827

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
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A Phase 2, Randomized Study to Evaluate Safety, Efficacy, and Optimal Dose of ABBV-400 in Combination With Fluorouracil, Folinic Acid, and Bevacizumab in Previously Treated Subjects With Unresectable Metastatic Colorectal Cancer

Condition: Unresectable Metastatic Colorectal Cancer
Primary Completion Date: 2026-10
Phase: II
Intervention/ Treatment: DRUG: **ABBV-400/ Bevacizumab/ Folinic Acid/ Fluorouracil/ Irinotecan**

Inclusion Criteria:
Diagnosis of histologically or cytologically confirmed unresectable metastatic colorectal cancer (mCRC). / Measurable disease per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1.
Exclusion Criteria:
.Harbor the BRAF V600E mutation. / dMMR+/MSI-H. / Progressed on only one first-line (1L) systemic treatment of combination chemotherapy in the metastatic setting with or without targeted therapy. Received anticancer therapy including chemotherapy, radiation therapy, immunotherapy, biologic, or any investigational therapy within 28 days or 5 half-lives of the drug (whichever is shorter) prior to the first dose of ABBV-400.
see Link:

clinicaltrials.gov/NCT06107413

Study Test Center	PI / SC	Phone	E-Mail
UKE Medical Oncology	PD Dr. med. Marianne Sinn Anna-Laura Rodemeister (SC)	040-7410 56882 040-7410 56545	ma.sinn@uke.de a.rodemeister@uke.de

Prospective, Randomized, Open, Multicenter Phase II Trial to Investigate the Efficacy of Trifluridine/Tipiracil Plus Panitumumab Versus Trifluridine/Tipiracil Plus Bevacizumab as First-line Treatment of Metastatic Colorectal Cancer: FIRE-8; AIO-KRK/YMO-0519

Condition: Metastatic Colorectal Cancer
Primary Completion Date: 2029-12
Phase: II
Intervention/ Treatment: DRUG: **Trifluridine/Tipiracil Hydrochloride**_BIOLOGICAL: **Panitumumab 20 milligram/mL/ Bevacizumab**

Inclusion Criteria:
Patient's signed informed consent / Patients ≥ 18 years at the time of signing the informed consent / Histologically confirmed adenocarcinoma of the colon or rectum / Metastatic colorectal cancer (mCRC) with at least one measurable lesion according to RECIST 1.1 in a computed tomography (CT) or magnetic resonance imaging (MRI) scan performed within 5 weeks prior to randomisation / Metastases are primarily unresectable or patient is unable/unwilling to undergo surgery / RAS (Rat Sarcoma) wild-type (Kirsten rat sarcoma (KRAS), exons 2, 3, 4 and Neuroblastoma RAS viral oncogene homologue (NRAS), exons 2, 3, 4) mCRC, proven in the primary tumor or metastasis. The RAS mutational status must be determined by means of a validated test method. / Patient is not eligible to undergo combination chemotherapy according to investigator's assessment or unwilling to undergo combination chemotherapy. / Eastern Cooperative Oncology Group (ECOG) performance status 0-2 / Adequate bone marrow, hepatic and renal organ function, defined by the **following laboratory test results**: Absolute neutrophil count ≥ 1.5 x 109/L (1500/µL) / Hemoglobin ≥ 80 g/L (8 g/dL) / Platelet count ≥ 75 x109/L (75,000/µL) without transfusion / Total serum bilirubin of ≤ 1.5 x upper limit of normal (ULN) / Aspartate aminotransferase (AST/GOT) and alanine aminotransferase (ALT/GPT) ≤ 2.5 × ULN; if liver function abnormalities are due to underlying liver metastasis, AST and ALT ≤ 5 × ULN / Calculated glomerular filtration rate (GFR) according to Cockcroft - Gault formula or according to MDRD formula ≥ 30 mL/min or serum creatinine ≤ 1.5 x ULN / Urine dipstick for proteinuria < 2+ (within 14 days prior to randomisation), unless a subsequent 24-hour urine collection demonstrates < 1 g of protein in 24 hours. / Patients without anticoagulation need to present with an INR <1.5 x ULN and partial thromboplastin time (PTT) <1.5 x ULN. Patients with anticoagulation may be enrolled if the patient receives the medication at a stable dose for at least 2 weeks before randomisation and provided that international normalized ratio (INR) and PTT are <1.5 x ULN.. / For females of childbearing potential (FCBP): negative pregnancy test within 14 days before randomisation and agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods with a failure rate of <1% per year during the treatment period and for at least 6 months after the last dose of study treatment. / A woman is considered to be of childbearing potential if she is postmenarcheal, has not reached a postmenopausal state (≥ 12 continuous months of amenorrhea with no identified cause other than menopause), and has not undergone surgical sterilization (removal of ovaries and/or uterus). Examples of contraceptive methods with a failure rate of < 1% per year include bilateral tubal ligation, male partner's sterilization, hormonal contraceptives that inhibit ovulation supplemented with a barrier method, hormone-releasing intrauterine devices, and copper intrauterine devices. The reliability of sexual abstinence should be evaluated in relation to the duration of the clinical trial and the preferred and usual lifestyle of the patient. Periodic abstinence (e.g., calendar, ovulation, symptothermal, or postovulation methods) and withdrawal are not acceptable methods of contraception. / For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating sperm, as defined below: With female partners of childbearing potential, men must remain abstinent or use a condom plus an additional contraceptive method that together result in a failure rate of <1% per year during the treatment period and for 6 months after the last dose of study treatment. In this regard, double barrier methods are not considered to have a failure rate of < 1%. Men must refrain from donating sperm during this same period. With pregnant female partners, men must remain abstinent or use a condom during the treatment period and for 6 months after the last dose of study medication to avoid exposing the embryo. The reliability of sexual abstinence should be evaluated in relation to the duration of the clinical trial and the preferred and usual lifestyle of the patient. Periodic abstinence (e.g., calendar, ovulation, symptothermal, or postovulation methods) and withdrawal are not acceptable methods of contraception.

Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT05007132

Study Test Center	PI / SC	Phone	E-Mail
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Anatomical Resection of Liver MetAstases iN patlents With RAS-mutated Colorectal cancer

Condition: Colorectal Liver Metastases
Estimated Completion Date: 2027-12
Phase: N/A
Intervention/ Treatment: PROCEDURE: **Resection of colorectal liver metastases**

Inclusion Criteria:
Colorectal cancer with RAS mutation (KRAS or NRAS) / Colorectal liver metastases (single or multiple) / Planned R0 resection of liver metastases (and primary tumor, if present) / Anatomical and non-anatomical liver resection technically feasible / Male and female patients, age ≥ 18 years / Written informed consent

Exclusion Criteria:
Extrahepatic metastases / Planned staged liver resection (e.g. two-stage hepatectomy) / Diagnosis of another cancer < 5 years prior to randomization Exceptions: curatively treated in situ cervical cancer, curatively resected non-melanoma skin cancer / Expected lack of compliance / Addiction or other illnesses which do not allow the person concerned to assess the nature and extent of the clinical trial and its possible consequences

see Link:

clinicaltrials.gov/NCT04678583

Study Test Center	PI / SC	Phone	E-Mail
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UKSH Lübeck General Surgery	PD Dr. med. Rüdiger Braun Julia Bertram (SC)	0451 500 401 01 0451 500 40457	Ruediger.Braun@uksh.de julia.bertram@uksh.de

Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Circulating Tumour DNA Based Decision for Adjuvant Treatment in Colon cancer Stage II Evaluation (CIRCULATE) AIO-KRK-0217

Condition: Colon cancer Stage II
Primary Completion Date: 2023-06
Phase: III
Intervention/ Treatment: DRUG: **Capecitabine**

Inclusion Criteria: Screening phase: Resected colon cancer stage II, OR Resected rectal cancer stage II, if there was no indication for radiotherapy (i.e. due to the localisation in the upper third of the rectum), so that the treatment follows the recommendations for colon cancer. / Patients, in whom the tumour stage is not yet know, can be enrolled into the screening. / Signed informed consent for the screening Phase. **Randomised phase:** Resected colon cancer stage II, OR resected rectal cancer stage II, if there was no indication for radiotherapy (i.e. due to the localisation in the upper third of the rectum), so that the treatment follows the recommendations for colon cancer. Known microsatellite or mismatch repair status. / Confirmation, that the ctDNA result is available. / Signed second informed consent (for the randomised phase).
Exclusion Criteria: Screening phase: :Patients with known microsatellite instability (MSI-H) or mismatch repair deficiency (dMMR). Known clinical high risk situation if it is regarded as certain indication for an adjuvant chemotherapy / Patients, who have an obvious contra-indication for adjuvant chemotherapy (i.e. due to the performance status, comorbidity, active second cancer or age). / It should be considered that patients with an age of more than 75 years frequently not fulfil criteria for adjuvant chemotherapy. / R1- or R2-status (patients with [still] unknown R-status can be screened). / Patients, in whom the randomisation or chemotherapy is unfeasible due to logistic reasons (travel distance, compliance). / Age < 18 years. / Pregnant or breast feeding patients. / **Randomised phase**: Patients with microsatellite instability (MSI-H) or mismatch repair deficiency (dMMR). / Known clinical high risk situation if it is regarded as certain indication for an adjuvant chemotherapy. / R1- or R2- status, or unknown R- status (Rx). / Number of investigated lymph nodes < 10. / WHO performance status ≥ 2. / Colon or rectal cancer with UICC stage III or IV Second cancer, except simultaneous or metachronous colon or rectal cancer with UICC stage ≤ I, curatively treated basal cell carcinoma or squamous cell carcinoma of the skin and in-situ cervical carcinoma / tumors with a disease free survival of more than five years. / Contra indications for chemotherapy, especially: Leukocytes < 3,0 Gpt/l. Neutrophil granulocytes < 1,5 Gpt/l. Thrombocytes < 100 Gpt/l. alanine aminotransferase (ALAT) or (aspartate aminotransferase) ASAT > 3x ULN. Creatinine clearance (calculated according Cockcroft-Gault) < 30 ml/min. / Comorbidities relevantly interfering with the prognosis of the patients, i.e.: heart insufficiency NYHA III/IV. relevant coronary heart disease, / Diabetes mellitus with late sequelae. / Organ, stem cell or bone marrow transplantation. / Known hypersensitivity to capecitabine In case of known hypersensitivity to oxaliplatin, the patients can participate, but not receive oxaliplatin. / Medication with brivudine, sorivudine or analogues in the last four weeks before planned treatment start. / Known dihydropyrimidine dehydrogenase (DPD)-deficiency. / Acute infections. / Known HIV- infections, known active hepatitis B or C-infection. / Participation at another interventional study for medical treatment during the last four weeks before randomization. / Neoadjuvant therapy before resection / Patients, in whom the randomisation or chemotherapy is unfeasible due to logistic reasons (travel distance, compliance). / Age < 18 years. / Pregnant or breast feeding patients. / Women of childbearing potential and men with partner with childbearing potential who are not willing to take appropriate precautions to avoid pregnancy with a highly effective method in case they are randomised to "chemotherapy“
see Link:

clinicaltrials.gov/NCT04089631

Study Test Center	PI / SC	Phone	E-Mail
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Klinikum Südstadt Rostock	Dr. med. Beate Krammer-Steiner Beatrice Engel (SC)	0381-4401-0 0381-4401-8614	beatrice.engel@kliniksued-rostock.de

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8 „FIRE-9 – PORT“ / AIO-KRK-0418

This is an open-label, randomized, controlled, multicenter, phase III study with two parallel arms. Patients with metastatic colorectal cancer after definite interventional therapy of all lesions are randomized in a 2:1 fashion (favoring active therapy) to investigate the efficacy, patient reported quality of life and safety of mFOLFOXIRI/mFOLFOX-6 as additive treatment (Arm A) versus active follow-up/surveillance (Arm B).

Condition: Colorectal cancer
Primary Completion Date: 2027-11
Phase: III
Intervention/ Treatment: DRUG: **mFOLFOX/ mFOLFOXIRI/ FOLFIRI/ CAPOX**

Inclusion Criteria:
Patient's signed informed consent. / Patient's age ≥18 years at the time of signing the informed consent. / Histologically confirmed adenocarcinoma of the colon or rectum. / Resected (R0 or R1) and/or effectively treated metastases (all techniques allowed) of colorectal cancer within 3-10 weeks before randomization (earlier randomisation allowed if at least 3 weeks interval between intervention and treatment start is guaranteed) AND resected primary tumor (synchronous or metachronous). In cases of synchronous metastases the interval of 3-10 weeks might be calculated following the removal of the primary tumor if this intervention was the last to address all tumor lesions. / Absence of significant active wound healing complications (if applicable) at randomization. / Resolved wound healing complications after resection/ablation are acceptable for inclusion into the trial. / No radiographic evidence of active metastatic disease at study entry in a CT and/or MRI scan not older than 10 weeks prior randomization. / Pre-surgery/ablation images are eligible for the study if all lesions have been addressed in the interval. / ECOG performance status 0-2. / Adequate bone marrow, hepatic and renal organ function, defined by the following laboratory test results: Absolute neutrophil count >= 1.5 x 109/L (1500/µL)/ Hemoglobin ≥ 80 g/L (8 g/dL)/ Platelet count ≥ 100 x109/L (100000/µL) without transfusion / Total serum bilirubin of ≤ 1.5 x upper limit of normal (ULN)/ Aspartate aminotransferase (AST/GOT) ≤ 3.0 × ULN. / Calculated glomerular filtration rate (GFR) according to Cockcroft-Gault formula or according to MDRD ≥ 50 mL/min or serum creatinine ≤ 1.5 x ULN / Patients without anticoagulation need to present with an INR < 1.5 x ULN and PTT < 1.5 x ULN. Patient with prophylactic or therapeutic anticoagulation are allowed into the trial. / Proficient fluorouracil metabolism as defined: / Prior treatment with 5-FU or capecitabine without unusual toxicity or/ If tested, normal DPD deficiency test according to the standard of the study site or/ If tested, in patients with DPD deficiency test with a CPIC activity score of 1.0-1.5 fluoropyrimidine/capecitabine dosage should be reduced by 50% /
For women of childbearing potential (WOCBP): negative pregnancy test within 14 days before randomization and agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods with a failure rate of < 1% per year during the treatment period and for at least 9 months after the last dose of Oxaliplatin or for at least 6 months after the last dose of all other study treatment. /
A woman is considered to be of childbearing potential if she is post-menarcheal, has not reached a postmenopausal state (≥ 12 continuous months of amenorrhea with no identified cause other than menopause), and has not undergone surgical sterilization (removal of ovaries and/or uterus). / Examples of contraceptive methods with a failure rate of < 1% per year include bilateral tubal ligation, male partner's sterilization, hormonal contraceptives that inhibit ovulation, hormone-releasing intrauterine devices, and copper intrauterine devices. /
For men: With female partners of childbearing potential, men must remain abstinent or use a condom plus an additional contraceptive method that together result in a failure rate of < 1% per year during the treatment period and for 6 months after the last dose of study treatment. Men must refrain from donating sperm during this same period.
see Link:

clinicaltrials.gov/NCT05008809

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Real-time use of artificial intelligence (CADEYE) in colorectal cancer monitoring of patients with Lynch syndrome – an international multicentre study

Condition: Malignant neoplasm of the digestive organs in the family history
Primary Completion Date: /
Phase: N/A
Intervention/ Treatment: Arm **1:Standard high-definition white light endoscopy (HD-WLE) in patients with Lynch syndrome undergoing colorectal cancer surveillance**/ Arm 2: **Standard high-definition white light endoscopy (HD-WLE) with additional automatic real-time detection (CAD EYE Fujifilm) in patients with Lynch syndrome undergoing colorectal cancer surveillance**

Inclusion Criteria:
All genders / Age 18+ / Written documented informed consent for voluntary participation in the study. / Patients who are able to follow the study instructions and are expected to attend and complete all required study visits. / Indication-specific Inclusion Criteria: Diagnosis of Lynch syndrome (proven presence)
Exclusion Criteria:
Patient is unable to understand the scope, significance and consequences of this clinical trial. / Patients with a physical or mental condition or systemic disease that, in the opinion of the investigator, poses a risk to the patient that could interfere with the study results or hinder participation in the clinical trial. / Simultaneous participation in another clinical trial with use of the medical device up to 30 days prior to participation in this clinical trial.
Additional exclusion criteria for women: Existing pregnancy / Indication-specific exclusion criteria: Previous extensive colorectal surgery (proctocolectomy or colectomy with ileorectal anastomosis). / Interval from the last colonoscopy to the planned examination less than 12 months. / Symptoms such as rectal bleeding, changes in bowel habit, unexplained weight loss, Anemia. / Concomitant inflammatory bowel disease
see Link:

drks.de/DRKS00030695

Study Test Center	PI / SC	Phone	E-Mail
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An Open-label Randomized Phase 3 Study of Tucatinib in Combination With Trastuzumab and mFOLFOX6 Versus mFOLFOX6 Given With or Without Either Cetuximab or Bevacizumab as First-line Treatment for Subjects With HER2+ Metastatic Colorectal Cancer

Condition: Metastatic Colorectal Neoplasms
Primary Completion Date: 2025-08-31
PHASE: III
Intervention/ Treatment: DRUG: **Tucatinib/ Trastuzumab/ Bevacizumab/ Cetuximab/ Oxaliplatin/ Leucovorin/ Fluorouracil**

Inclusion Criteria:
Histologically and/or cytologically confirmed adenocarcinoma of the colon or rectum which is locally advanced unresectable or metastatic / Able to provide the most recently available formalin-fixed paraffin-embedded (FFPE) tumor tissue blocks (or freshly sectioned slides) obtained prior to treatment initiation to a central laboratory / If archival tissue is not available, a newly-obtained baseline biopsy of an accessible tumor lesion is required within 35 days prior to start of study treatment / HER2+ disease as determined by a tissue based assay performed at a central laboratory. / Participant has rat sarcoma viral oncogene homolog wild-type (RAS WT) disease as determined by local or central testing. For central RAS analysis, tissue sample must be analyzed within 1 year of biopsy date. / Radiographically **measurable disease per RECIST v1.1 with:** At least one site of disease that is measurable and that has not been previously irradiated, or / If the participant has had previous radiation to the target lesion(s), there must be evidence of progression since the radiation / Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1 / CNS Inclusion - based on contrast brain magnetic resonance imaging, participants may have **any of the following**: No evidence of brain metastases / Previously treated brain metastases which are asymptomatic /
Exclusion Criteria:
Prior systemic anticancer therapy for colorectal cancer (CRC) in the locally advanced unresectable or metastatic setting; note that participants may have received a maximum of 2 doses of mFOLFOX6 in the locally advanced/unresectable or metastatic setting prior to randomization. / Note: May have received chemotherapy for CRC in the adjuvant setting if it was completed >6 months prior to enrollment / Radiation therapy within 14 days prior to enrollment (or within 7 days in the setting of stereotactic radiosurgery) / Previous treatment with anti-HER2 therapy / Ongoing Grade 3 or higher neuropathy / Active or untreated gastrointestinal (GI) perforation at the time of screening.
see Link:

clinicaltrials.gov/NCT05253651

Study Test Center	PI / SC	Phone	E-Mail
Hämatolisch-Onkologische Praxis Eppendorf	Prof. Dr. med. Alexander Stein Dr. med. Eray Gökkurt	040-360352222	stein@hope-hamburg.de goekkurt@hope-hamburg.de

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Effectiveness of supplementation of a probiotic (OMNi-BiOTiC 10) together with individual nutritional counselling with a focus on a prebiotic diet compared to individual nutritional counselling with a focus on a prebiotic diet alone for improving gastrointestinal symptoms in colorectal cancer survivors - A prospective double-blind randomised placebo-controlled intervention study

Condition: Functional bowel disorder, unspecified
Primary Completion Date: /
Phase: N/A
Intervention/ Treatment: Arm 1: **‘Prebiotic dietary advice’ rich in fibre from whole grains and fruit & vegetables + probiotics supplement**
Arm 2: ‘**Prebiotic dietary advice’ rich in fibre from whole grains and fruit & vegetables + placebo**

Inclusion Criteria:
All genders / Patients after colorectal cancer (incl. rectum) with gastrointestinal complaints (need according to screening) / 3 months -5 years after completion of treatment/ life expectancy ≥ 6 months
age ≥ 18 years / Written declaration of consent available

Exclusion Criteria:
Active infection > grade 2 NCI-CTCAE V5.0 / Severe systemic disease: e.g. uncontrolled hypertension (systolic blood pressure > 160 mmg Hg, diastolic > 100 mm Hg; > grade 2 CTCAE V 5.0) **or** uncontrolled hyperglycaemia > grade 3 CTCAE V 5.0 **or** hypoglycaemia > grade 2 CTCAE V 5.0, symptomatic coronary heart disease > grade 2 CTCAE V 5.0 / cardiac insufficiency NYHA III - IV/ / Antibiotic treatment in the last 8 weeks / Uncontrolled diabetes type I or II / Need for immunosuppressive therapy, severe non-healing wounds, ulcers or bone fractures / Female subjects who are pregnant, breastfeeding or who wish to become pregnant; and sexually active male or female patients who are unwilling to use highly effective contraceptive methods / Any condition that, in the opinion of the investigator, would interfere with the evaluation of the study treatment or the interpretation of patient safety or study results / Any psychological, familial or sociological condition that would prevent compliance with the protocol. / Participation in another clinical trial with an investigational product in the 15 days prior to enrolment / Patients who have been detained or involuntarily institutionalised due to a court order or by the authorities (German Drug Law § 40) / Parenteral nutrition, enteral supplementary nutrition (nutrition via PEG or PEJ) or high-calorie liquid nutrition (if ≥ 50% of the energy requirement is covered by liquid nutrition) after therapy for tumour cachexia/ - Presence of intestinal stenosis.
see Link:

drks.de/DRKS00025802

Study Test Center	PI / SC	Phone	E-Mail
UKE UCC Hamburg	PD Dr. med. Marianne Sinn	040-7410-56882	ma.sinn@uke.de

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Universitätsklinikum Hamburg-Eppendorf

FUTURE Platform Trial - A Phase II Platform Trial of Futibatinib in Combination With (Chemo)Immunotherapy in Colorectal Cancer and Other Solid Tumor Entities

Condition: Colorectal Cancer
Primary Completion Date: 2027-09
Phase: II
Intervention/ Treatment: DRUG: **Futibatinib orally administered/ Tislelizumab (i.v. 200mg)**

Inclusion Criteria:
Patient* provides signed informed consent. /Patient is ≥ 18 years at the time of given informed consent. / Patient has a histologically proven solid tumor: / Specific for FUTURE-001: Histological or cytological confirmation of colorectal adenocarcinoma that is unresectable and/or metastatic with known RAS-, BRAF and MSI- status. / Specific for FUTURE-001: Patient must agree to participation in the accompanying translational research program. / Specific for FUTURE-001: Patient did not receive previous therapy in palliative setting (1st line situation). / Patient has ECOG Performance status ≤ 1. / Patient has adequate blood count, liver-enzymes, and renal function: / ANC > 1,500 cells/µL without the use of hematopoietic growth factors / Platelet count ≥ 100 x 109/L (>100,000 per mm3) / Hemoglobin ≥ 9 g/dL, transfusion allowed / Serum total bilirubin ≤ 1.5x institutional upper normal limit (ULN) (or < 2 x ULN in case of liver involvement or Gilbert's disease) / AST (SGOT)/ALT (SGPT) ≤ 2.5 x institutional ULN without existing liver metastases, or ≤ 5 x UNL in the presence of liver metastases; AP ≤ 5 x ULN / Patients not receiving therapeutic anticoagulation must have an INR ≤ 1.5 ULN and aPTT ≤ 1.5 ULN. The use of full dose anticoagulants is allowed as long as the INR or PTT is within therapeutic limits (according to the medical standard in the institution) and the patient has been on a stable dose for anticoagulants for at least three weeks at the time of inclusion / Serum Creatinine ≤ 1.5 x ULN and a calculated creatinine clearance rate ≥ 50 mL /min / Patient has serum calcium and phosphate levels within normal range. / Female patients of childbearing potential or male patients with female partners of childbearing potential must agree to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of <1% per year during the treatment period and in FUTURE-001 for at least 1 week after last dose of futibatinib, 6 months after the last dose of chemotherapy or 4 months after last dose of tislelizumab, whatever is later. Male patients should refrain from sperm donation/ cryopreservation throughout this period and male patients with a pregnant partner must agree to remain abstinent or to use a condom for the duration of the pregnancy. Female patients of child-bearing potential must have a negative pregnancy test within the last 7 days prior to the start of trial therapy. / Patient is willing and able to comply with the protocol (including contraceptive measures) for the duration of the study including undergoing treatment and scheduled visits and examinations including follow up. / There is no data that indicates a specific gender distribution. Therefore, patients are included regardless of their gender.

Exclusion Criteria:

clinicaltrials.gov/NCT06722183

Study Test Center	PI / SC	Phone	E-Mail
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Urothelial bladder cancer

continue...

Contact at UCC Hamburg
Prof. Dr. med. Gunhild von Amsberg, Tel.: 0152-22815585

A Randomized Phase II, Double-Blind, Multicenter Study Evaluating the Efficacy and Safety of Autogene Cevumeran Plus Nivolumab Versus Nivolumab as Adjuvant Therapy in Patients With High-Risk Muscle-Invasive Urothelial Carcinoma

Condition: Muscle Invasive Urothelial cancer
Primary Completion Date: 2028-11-06
Phase: II
Intervention/ Treatment: Drug: **Autogene Cevumeran/ Nivolumab/ Saline**

Inclusion Criteria:
Histologically confirmed muscle-invasive UC (also termed TCC) of the bladder or upper urinary tract / TNM classification (UICC/AJCC 7th edition) at pathological examination of surgical resection specimen of (y)pT3-4 or (y)pN+ and M0 / Surgical resection of MIUC of the bladder or upper tract / Participants who have not received prior neoadjuvant cisplatin chemotherapy (NAC) must be ineligible to receive adjuvant cisplatin therapy due to patient refusal, cisplatin ineligibility or investigator decision / Tumor tissue must be provided for biomarker analysis / Absence of residual disease and absence of metastasis, as confirmed by a negative baseline Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) scan of the pelvis, abdomen, and chest no more than 28 days prior to randomization. / Full recovery from cystectomy or nephroureterectomy within 120 days following surgery / Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 / Negative HIV test at screening / No evidence of active hepatitis B, defined as having a negative hepatitis B surface antigen (HbsAg) test at screening / Negative hepatitis C virus (HCV) antibody test at screening, or a positive HCV antibody test followed by a negative HCV RNA test at screening

Exclusion Criteria:
Partial cystectomy in the setting of bladder cancer primary tumor or partial nephroureterectomy in the setting of renal pelvis primary tumor / Any approved anti-cancer therapy, including chemotherapy, or hormonal therapy within 3 weeks prior to initiation of study treatment / Any prior neoadjuvant immunotherapy / Adjuvant chemotherapy or radiation therapy for UC following surgical resection / Malignancies other than UC within 5 years prior to randomization / Treatment with a live, attenuated vaccine within 4 weeks prior to initiation of study treatment

see Link:

clinicaltrials.gov/NCT06534983

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Phase 3, Randomized Study Evaluating the Efficacy and Safety of TAR-210 Erdafitinib Intravesical Delivery System Versus Single Agent Intravesical Chemotherapy in Participants With Intermediate-risk Non-muscle Invasive Bladder Cancer (IR-NMIBC) and Susceptible FGFR Alterations

Condition: Non-Muscle Invasive Bladder Cancer
Primary Completion Date: 2028-06-28
Phase: III
Intervention/ Treatment: Drug: **Gemcitabine/ MMC**_COMBINATION PRODUCT: **TAR-210**

Inclusion Criteria:
Have a histologically confirmed diagnosis (within 90 days of randomization) of IR-NMIBC with at least one of the following criteria fulfilled: a. Ta low grade (LG)/ Grade 1 (G1): primary or recurrent, b. Ta LG/G2: primary or recurrent and c. Greater than or equal to (>=) 1 of the following risk factors: i. Multiple Ta LG tumors, ii. Solitary LG tumor >= 3 cm, iii. Early recurrence (less than [<] 1 year), iv. Frequent recurrence (greater than [>] 1 per year), v. Recurrence after prior adjuvant intravesical treatment (single perioperative dose of chemotherapy does not fulfill this risk factor) / Have a susceptible fibroblast growth factor receptor (FGFR) mutation or fusion either by urine testing or tumor tissue testing (from TURBT tissue), as determined by central or local testing / Participants must be willing to undergo all study procedures (e.g., multiple cystoscopies from Screening through the end of study and TURBT for assessment of recurrence/progression) and receive the assigned treatment, including intravesical chemotherapy if randomized into that arm. / Visible papillary disease must be fully resected prior to randomization and absence of disease must be documented at Screening cystoscopy / Can have a prior or concurrent second malignancy (other than the disease under study) which natural history or treatment is unlikely to interfere with any study endpoints of safety or the efficacy of the study treatment / Have an Eastern Cooperative Oncology Group performance status of 0 to 2

Exclusion Criteria:
Known allergies, hypersensitivity, or intolerance to any study component or its excipients, including: a. Erdafitinib excipients; b.TAR-210 drug delivery system constituent materials ; c. urinary placement catheter materials; d. MMC or chemically related drugs; e. Gemcitabine or chemically related drugs / Presence of any bladder or urethral anatomic feature (that is, urethral stricture) that, in the opinion of the investigator, may prevent the safe insertion, indwelling use, removal of TAR-210 or passage of a urethral catheter for intravesical chemotherapy / Polyuria with recorded 24-hour urine volumes > 4000 milliliters (mL) / Current indwelling urinary catheters, however, intermittent catheterization is acceptable / Had major surgery or had significant traumatic injury and/or not fully recovered within 4 weeks before first dose (TURBT is not considered major surgery)

see Link:

clinicaltrials.gov/NCT06319820

Study Test Center	PI / SC	Phone	E-Mail
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Prostate cancer

continue...

Contact at UCC Hamburg
Prof. Dr. med. Gunhild von Amsberg, Tel.: 0152-22815585

A Phase 3, Two-part, Randomized, Open-label, Adaptive Study Comparing BMS-986365 Versus Investigator's Choice of Therapy Comprising Either Docetaxel or Second Androgen Receptor Pathway Inhibitor (ARPI), in Participants With Metastatic Castration-resistant Prostate Cancer (mCRPC) - rechARge

Condition: Metastatic Castration-resistant Prostate cancer
Estimated Completion Date: 2027-09-12
Phase: III
Intervention/ Treatment: DRUG: **BMS-986365/ Enzalutamide/ Abiraterone/ Docetaxel/ Predinsone/Prednisolone**

Inclusion Criteria:
Pathology-verified prostate adenocarcinoma / Pathology material available for central review / International Society of Urological Pathology (ISUP) grade 1 to 3 / Localised prostate cancer. **a.** No clinical suspicion of prostate cancer outside the prostatic bed at the time of enrolment into the trial; and **b.** If N- and M- staging has been performed (at the initial staging or at any later time points), the results must be N0 and M0. / Prostate biopsy within 1 to 6 months prior to the first planned day of injection of 64Cu-DOTA-AE105 (patients with a biopsy within the last month are excluded to avoid possible inflammation artefacts on the PET scan) a. The biopsy can be part of the primary staging, a confir matory biopsy, or serial biopsy conducted as part of an AS or watchful waiting program. b. At least 1 core must be MRI-guided.

Exclusion Criteria:
Any prior treatment for prostate cancer (surgery, external beam radiation therapy, brachytherapy, hormone therapy, or chemotherapy / Chronic prostatitis (any signs or symptoms of chronic bacterial prostatitis or chronic pelvic prostatitis and pain syndrome, or known diagnosis of asymptomatic inflammatory prostatitis). / Acute infections within the prostatic bed or lower urinary tract infections. / Participants have inadequate bone marrow, kidney, liver, heart, or lung function

see Link:

clinicaltrials.gov/NCT06764485

Study Test Center	PI / SC	Phone	E-Mail
UKE Medical Oncology	Prof. Dr. med. Gunhild von Amsberg Frank Knauer (SC)	0152-22815585 040 7410 – 53994	g.von-amsberg@uke.de f.knauer@uke.de

MK-2400-01A Substudy: A Phase 1/2, Open-label Umbrella Substudy of MK-2400-U01 Master Protocol to Evaluate the Safety and Efficacy of Ifinatamab Deruxtecan-based Treatment Combinations or Ifinatamab Deruxtecan Alone in Participants With Metastatic Castration-resistant Prostate Cancer (mCRPC) (IDeate-Prostate02)

Condition: Castration-resistant Prostate cancer/ Metastatic
Estimated Completion Date: 2030-02-18
Phase: I/II
Intervention/ Treatment: DRUG: **Docetaxel/ Ifinatamab Deruxtecan/ MK-5684/ Abiraterone/ Enzalutamide**

Inclusion Criteria:
Has histologically- or cytologically-confirmed adenocarcinoma of the prostate without small cell histology / Has prostate cancer progression while on androgen deprivation therapy (ADT) (or post bilateral orchiectomy) within 6 months before Screening / Has current evidence of metastatic disease / Has received prior treatment with 1 or 2 androgen receptor pathway inhibitors (ARPIs) and progressed during or after treatment / Participants receiving bone resorptive therapy (including, but not limited to bisphosphonate or denosumab) must have been on stable doses for ≥4 weeks before allocation/randomization / An Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1 assessed within 10 days before allocation/randomization / Has prior treatment with poly-ADP-ribose polymerase inhibitors (PARPi) if indicated by local approved regimen or were deemed ineligible to receive PARPi by the investigator

Exclusion Criteria:
History of (non-infectious) interstitial lung disease (ILD)/pneumonitis that required steroids, or has current ILD/pneumonitis or suspected ILD/pneumonitis / Clinically severe pulmonary compromise resulting from intercurrent pulmonary illnesses / Uncontrolled or significant cardiovascular disease / History of pituitary dysfunction / Poorly controlled diabetes mellitus / History or current condition of adrenal insufficiency (eg, Addison's disease) / Has received prior treatment with taxane-based chemotherapy agent for metastatic castration-resistant prostate cancer (mCRPC). / Chronic steroid treatment (dose of >10 mg daily prednisone equivalent), except for low-dose inhaled steroids (for asthma/chronic obstructive pulmonary disease), topical steroids (for mild skin conditions), or intra-articular steroid injections / Received prior radiotherapy within 2 weeks of start of study intervention, or has radiation-related toxicities, requiring corticosteroids / Known additional malignancy that is progressing or has required active treatment within the past 3 years / Known active central nervous system (CNS) metastases and/or carcinomatous meningitis / Active autoimmune disease that has required systemic treatment in the past 2 years / History of allogeneic tissue/solid organ transplant
see Link:

clinicaltrials.gov/NCT06863272

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Phase 3, Open-label Study of Ifinatamab Deruxtecan Versus Docetaxel in Participants With Metastatic Castration-Resistant Prostate Cancer (mCRPC) (IDeate-Prostate01)

Condition: Prostate cancer/ Prostatic Neoplasms
Estimated Completion Date: 2028-06-26
Phase: III
Intervention/ Treatment: DRUG: **Ifinatamab Deruxtecan/ Docetaxel/ Prednisone**

Inclusion Criteria:
Has diagnosis of metastatic castration-resistant prostate cancer (mCRPC) / Has prostate cancer progression while on androgen deprivation therapy (ADT) (or post bilateral orchiectomy) within 6 months prior to entering the study / Has received prior treatment with 1 or 2 androgen receptor pathway inhibitor (ARPI) and progressed during or after at least 8 weeks of treatment

Exclusion Criteria:
History of (non-infectious) interstitial lung disease (ILD)/pneumonitis that required steroids / Has uncontrolled or significant cardiovascular disease / Has received prior treatment with a taxane-based chemotherapy agent for mCRPC

see Link:

clinicaltrials.gov/NCT06925737

Study Test Center	PI / SC	Phone	E-Mail
UKE Medical Oncology	Prof. Dr. med. Gunhild von Amsberg Frank Knauer (SC)	0152-22815585 040 7410 – 53994	g.von-amsberg@uke.de f.knauer@uke.de

A Phase 3 Randomized, Double-blind, Placebo-controlled Study of Pasritamig (JNJ-78278343), a T Cell Redirecting Agent Targeting Human Kallikrein 2, + Best Supportive Care Versus Best Supportive Care for Metastatic Castration-resistant Prostate Cancer

Condition: Metastatic Castration-resistant Prostate Neoplasms
Estimated Completion Date: 2028-05-30
Phase: III
Intervention/ Treatment: DRUG: **Best Supportive Care (BSC)**_BIOLOGICAL: **Pasritamig**_ OTHER: **Placebo**

Inclusion Criteria:
Histologically confirmed adenocarcinoma of the prostate / Metastatic castration-resistant prostate cancer (mCRPC): Disease that is metastatic either to bone, any lymph node, or both without clear evidence of metastasis to visceral organs at the time of screening / PSA greater than or equal to (>=) 2 nanogram per milliliter (ng/mL) at screening / In the opinion of the investigator, the next best treatment option is a clinical trial / Participants should have had all life-prolonging therapies for which they are clinically eligible in the opinion of the investigator and to which they have access. Prior therapies could have been given in any disease setting (not limited to mCRPC). In particular, prior treatment specifications include receipt of the following: Androgen-receptor pathway inhibitor (ARPI): Must have progressed on at least 1 ARPI and unlikely to benefit from retreatment with another ARPI / Taxanes: Should have received at least 2 previous taxane-based regimens. If a participant has received only 1 taxane regimen, the participant is eligible if: / Cabazitaxel is not available / The participant's physician deems the participant unsuitable to receive a second taxane regimen due to toxicity risk or prior intolerance Note: a taxane-based regimen consists of at least 2 cycles of a taxane (either as a single agent or in combination with other therapies) administered within the same 2-month period. Radioligand therapy: Should have been previously treated with at least 1 dose of Prostate-specific membrane antigen (PSMA)-targeted lutetium radioligand therapy (eg, lutetium Lu-177 vipivotide tetraxetan), unless one of the following applies: / PSMA-targeted lutetium radioligand therapy is unavailable, not accessible, or not clinically indicated. / The participant's physician deems the participant unsuitable to receive PSMA-targeted lutetium radioligand therapy. / Polyadenosine diphosphate-ribose polymerase inhibitors (PARPi): Should have been previously treated with PARPi, if the participant has a known germline or somatic BRCA mutation and treatment is available / Prior orchiectomy or medical castration (receiving ongoing ADT with a GnRH analog [agonist or antagonist]) prior to the first dose of study treatment and must continue this therapy throughout the treatment phase / Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 / Participants are eligible if they have the following values: / A) eGFR >= 30 milliliters per minute (mL/min) B) Alanine Aminotransferase (ALT) and Aspartate Aminotransferase (AST) less than or equal to (<=) 5 times the Upper Limit of Normal (ULN) C) Serum total bilirubin <= 3 * ULN D) Absolute neutrophil count (ANC) >= 1.0 *10^9/per liter (L) E) Hemoglobin >= 8.0 grams per deciliter (g/dL) F) Platelet count >= 75 * 109/L

Exclusion Criteria:
Venous thromboembolic events within 1 month prior to the first dose of study treatment; uncomplicated (Grade <= 2) deep vein thrombosis is not exclusionary / Active autoimmune disease within the past 12 months that requires systemic immunosuppressive medications (eg, chronic corticosteroid, methotrexate, or tacrolimus) / Clinically significant pulmonary compromise, particularly a requirement for supplemental oxygen use (>2 liters per minute (L/min) by nasal cannula) to maintain adequate oxygenation / Prior or concurrent second malignancy (other than the disease under study) for which natural history or treatment could likely interfere with any study endpoints of safety or the efficacy of the study treatment(s) / Any of the following within 6 months prior to first dose of study treatment:
A) Myocardial infarction B) Severe or unstable angina C) Clinically significant ventricular arrhythmias D) Congestive heart failure (New York Heart Association class II to IV) E) Transient ischemic attack F) Cerebrovascular accident / - Prior treatment with any CD3-directed therapy

see Link:

clinicaltrials.gov/NCT07164443

Study Test Center	PI / SC	Phone	E-Mail
UKE Medical Oncology	Prof. Dr. med. Gunhild von Amsberg Negena Nezami (SC)	0152-22815585 **0152 22800148**	g.von-amsberg@uke.de Negena.Nezami@uke.de

A Double-blind Randomised Phase III Trial Evaluating the Efficacy of ADT +/- Darolutamide in de Novo Metastatic Prostate Cancer Patients With Vulnerable Functional Ability and Not Elected for Docetaxel or Androgen Receptor Targeted Agents

Condition: Metastatic Prostate cancer Metastatic
Estimated Completion Date: 2028-03
Phase: III
Intervention/ Treatment: DRUG: **Darolutamide 300 mg/ Placebo/ Androgen deprivation therapy**

Inclusion Criteria:
Signed a written informed consent form prior to any trial specific procedures. / Men with histologically or cytologically confirmed adenocarcinoma of the prostate. / Aged ≥18 years old at the time of signing informed consent. / De novo metastatic disease defined by clinical or radiological evidence of metastases. / Note: For patients with nodal metastases only, **only patients with extra-pelvic enlarged lymph nodes (lymph nodes located above the iliac bifurcation) can be included if they have either:**At least one extra-pelvic lymph node ≥2 cm / At least one extra-pelvic lymph node ≥1 cm if the patients also have at least one pelvic lymph node ≥2 cm / Measurable disease or bone lesions that are evaluable according to PCWG3 criteria. / Ineligible for treatment with all of the following drugs: docetaxel, / biraterone, enzalutamide, apalutamide; **AND meets at least one of the following frailty criteria**: / Activities of daily living (ADL) assessment (excluding urinary incontinence question) score 3 or 4/5, or; / 4-Instrumental activities of daily living (4-IADL) assessment score 2 or 3/4, or; / A Grade 3 event on the Cumulative Illness Score Rating-Geriatrics (CISR-G) questionnaire, or; / Body mass index (BMI) ≤21 kg/m² and/or >5% weight loss in the last 6 months, or; / Timed up and go test (TUG) >14 sec. Nota Bene: Regarding CISR-G assessment, more specifically genitourinary scoring, score N°4 is not applicable. 1.Adequate bone marrow function: haemoglobin ≥80 g/L, white blood cells ≥3.0 x10⁹/L and platelets ≥80 x10⁹/L. / Adequate liver function: alanine aminotransferase (ALT) <2 x upper limit of normal (ULN) and bilirubin <1.5 x ULN, (or if bilirubin is between 1.5-2 x ULN, they must have a normal conjugated bilirubin). For patients with documented liver metastasis, ALT <5 x ULN is acceptable. / Adequate renal function: calculated creatinine clearance >30 ml/min (using the Modification of Diet in Renal Disease [MDRD] or Chronic Kidney Disease Epidemiology Collaboration [CKD EPI] method). / For sexually active men, agreement to use adequate contraception for the duration of trial participation and up to 2 weeks after completing study treatment. / Affiliated to the social security system or in possession of equivalent private health insurance (according to local regulations for participation in clinical trials). / Willing and able to comply with the protocol for the duration of the trial including undergoing treatment and scheduled visits, and examinations including follow-up.
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT04916613

Study Test Center	PI / SC	Phone	E-Mail
UKE Medical Oncology	Prof. Dr. med. Gunhild von Amsberg Frank Knauer (SC)	0152-22815585 **040 7410 53994**	g.von-amsberg@uke.de f.knauer@uke.de

A Phase 3, Open-label, Multicenter, Randomized Study of Xaluritamig vs Cabazitaxel or Second Androgen Receptor-Directed Therapy in Subjects With Metastatic Castration-Resistant Prostate Cancer Previously Treated With Chemotherapy

Condition: Metastatic Castration-resistant Prostate cancer
Estimated Completion Date: 2029-01-02
Phase: III
Intervention/ Treatment: DRUG: **Xaluritamig/ Abiraterone/ Enzalutamide/ Cabazitaxel**

Inclusion Criteria:
Participant has provided informed consent prior to initiation of any study-specific activities/procedures. / Age ≥ 18 years (or ≥ legal age within the country if it is older than 18 years) at the time of signing the informed consent. / Participant must have histological, pathological, and/or cytological confirmation of adenocarcinoma of the prostate. Mixed histologies (eg, adenocarcinoma with neuroendocrine component) are not permitted. / mCRPC with ≥ 1 metastatic lesion that is present on baseline computed tomography (CT), magnetic resonance imaging (MRI), or bone scan imaging obtained within 28 days prior to enrollment. / **Evidence of progressive disease, defined as 1 or more PCWG3 criteria:** Serum PSA progression defined as 2 consecutive increases in PSA over a previous reference value measured at least 1 week prior. The minimal start value is 2.0 ng/mL. / Soft-tissue progression defined as an increase ≥ 20% in the sum of the diameter (SOD) (short axis for nodal lesions and long axis for non-nodal lesions) of all target lesions based on the smallest SOD since treatment started or the appearance of one or more new lesions or unequivocal progression of existing non-target lesions. / Progression of bone disease: defined by the appearance of at least 2 new bone lesion(s) by bone scan (as per the 2+2 PCWG3 criteria). / Participants must have had a prior orchiectomy and/or ongoing androgen-deprivation therapy and a castrate level of serum testosterone (< 50 ng/dL or < 1.7 nmol/L). / Prior progression on at least one ARDT (enzalutamide, abiraterone, apalutamide, darolutamide).
•Prior treatment with only one taxane therapy in the mCRPC setting. Note: Prior treatment with docetaxel in the metastatic hormone-sensitive prostate cancer (mHSPC) setting is permitted; however, participants must have also received one, and only one, taxane therapy in the mCRPC setting. / Eastern Cooperative Oncology Group performance status (ECOG PS) of 0 or 1. / Adequate organ function.
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT06691984

Study Test Center	PI / SC	Phone	E-Mail
UKE Medical Oncology	Prof. Dr. med. Gunhild von Amsberg Frank Knauer (SC)	0152-22815585 040 7410 53994	g.von-amsberg@uke.de f.knauer@uke.de

An Open-label, Two-part, Phase 2 Clinical Trial to Investigate the Safety and Diagnostic Performance of uPAR PET Imaging for Non-invasive Classification of ISUP Grades Among Patients With Localised, Untreated Prostate Cancer.

Condition: Prostate cancer
Estimated Completion Date: N/A
Phase: II
Intervention/ Treatment: DRUG: **64Cu-DOTA-AE105**

Inclusion Criteria:
Pathology-verified prostate adenocarcinoma / International Society of Urological Pathology (ISUP) grade 1 to 3 / Localised prostate cancer (N0 and M0 status) (only required for ISUP 3 patients) / Newly diagnosed patients: Staging must be performed within 6 months from enrolment into the trial. / Active surveillance: N0/M0 at the time of diagnosis and no clinical suspicion of prostate cancer outside the prostatic bed at the time of enrolment into the trial. / Eastern Cooperative Oncology Group (ECOG) performance status 0-2 / Prostate biopsy within 1 to 6 months (patients with a biopsy within the last month are excluded to avoid possible inflammation artefacts on the PET scan) / The biopsy can be part of the primary staging, a confirmatory biopsy, or serial biopsy as part of an AS. / At least 1 core must be MRI-guided.
Exclusion Criteria:
Any prior treatment for prostate cancer (surgery, external beam radiation therapy, brachytherapy, hormone therapy, or chemotherapy) / Chronic prostatitis (any signs or symptoms of chronic bacterial prostatitis or chronic pelvic prostatitis and pain syndrome, or known diagnosis of asymptomatic inflammatory prostatitis) / Acute infections within the prostatic bed or lower urinary tract infections / Participants have inadequate bone marrow, kidney, liver, heart, or lung function:
see Link:

clinicaltrials.gov/NCT06474806

Study Test Center	PI / SC	Phone	E-Mail
UKE Martini Klinik	Prof. Dr. med. Tobias Maurer Andrea Benz (SC)	040 7410 – 51352 040 7410 – 51311	t.maurer@uke.de a.benz@uke.de

A Phase II, Randomized, Open-label, Multi-center Study of JSB462 (Luxdegalutamide) in Combination With Abiraterone in Adult Male Patients With Metastatic Hormone-sensitive Prostate Cancer (mHSPC)

Condition: Metastatic Hormone-sensitive Prostate Cancer
Estimated Completion Date: 2032-02-26
Phase: II
Intervention/ Treatment: DRUG: **JSB462/ Abiraterone/ Enzalutamide**

Inclusion Criteria:
Pathology-verified prostate adenocarcinoma / International Society of Urological Pathology (ISUP) grade 1 to 3 / Localised prostate cancer (N0 and M0 status) (only required for ISUP 3 patients) / Newly diagnosed patients: Staging must be performed within 6 months from enrolment into the trial. / Active surveillance: N0/M0 at the time of diagnosis and no clinical suspicion of prostate cancer outside the prostatic bed at the time of enrolment into the trial. / Eastern Cooperative Oncology Group (ECOG) performance status 0-2 / Prostate biopsy within 1 to 6 months (patients with a biopsy within the last month are excluded to avoid possible inflammation artefacts on the PET scan) / The biopsy can be part of the primary staging, a confirmatory biopsy, or serial biopsy as part of an AS. / At least 1 core must be MRI-guided.
Exclusion Criteria:
Any prior treatment for prostate cancer (surgery, external beam radiation therapy, brachytherapy, hormone therapy, or chemotherapy) / Chronic prostatitis (any signs or symptoms of chronic bacterial prostatitis or chronic pelvic prostatitis and pain syndrome, or known diagnosis of asymptomatic inflammatory prostatitis) / Acute infections within the prostatic bed or lower urinary tract infections / Participants have inadequate bone marrow, kidney, liver, heart, or lung function:
see Link:

clinicaltrials.gov/NCT06991556

Study Test Center	PI / SC	Phone	E-Mail
UKE Medical Oncology	Prof. Dr. med. Gunhild von Amsberg Lara Hiecke (SC)	0152-22815585 0152 228 019 62	g.von-amsberg@uke.de Lar.Hiecke@uke.de

A Phase II, Randomized, Open-label, Multi-center Study of JSB462 (Luxdegalutamide) in Combination With Abiraterone in Adult Male Patients With Metastatic Hormone-sensitive Prostate Cancer (mHSPC)

Condition: Prostate Cancer Patients Treated by Radiotherapy
Estimated Completion Date: 2026-10-31
Phase: N/A
Intervention/ Treatment: DEVICE: **Reminder App**

Inclusion Criteria:
Histologically proven high-risk prostate cancer / Indication for definitive normo-fractionated radiotherapy / Possession of a smart phone and the ability to use it / Bladder volume at CT-simulation <200 ml / Male gender / Age ≥18 years / Written informed consent / Capacity of the patient to contract

Exclusion Criteria:
Radiotherapy of pelvic lymph nodes / Expected non-compliance

see Link:

clinicaltrials.gov/NCT06653751

Study Test Center	PI / SC	Phone	E-Mail
UKSH Lübeck Radiotherapy	Prof. Dr. med. Dirk Rades		Dirk.Rades@uksh.de

Image-guided Focal Dose Escalation in Patients With Primary Prostate Cancer Treated With Primary External Beam Hypofractionated Stereotactic Radiation Therapy (HypoFocal-SBRT) - a Prospective, Multicenter, Randomized Phase III Study

Condition: Prostate Cancer
Estimated Completion Date: N/A
Phase: N/A
Intervention/ Treatment: RADIATION: **Radiotherapy (RT) Arm A - IMRT/IGRT/SBRT/ Radiotherapy (RT) Arm B - IMRT/IGRT**

Inclusion Criteria:
Histologically confirmed adenocarcinoma of the prostate (histological confirmation can be based on tissue taken at any time, but a re-biopsy should be considered if the biopsy is more than 12 months old) / Primary localized PCa (cN0 and cM0 in mpMRI and PSMA PET): / high- or very high-risk according to NCCN v2.2021 (see 20.3) OR / unfavorable intermediate-risk disease according to NCCN v2.2021 (see 20.3) / Signed, written informed consent for HypoFocal-SBRT study / Age > 18 years / Previously conducted PSMA-PET/CT and mpMRI scans or PSMA-PET/MR, fulfilling standard requirements for PCa (see also 6.5) / ECOG Performance score 0 or 1 / IPSS Score ≤15 / Prostate volume ≤75 ml at RT planning

Exclusion Criteria:
Evidence of neuroendocrine tumor cells / Prior radiotherapy to the prostate or pelvis / Prior radical prostatectomy / Prior focal therapy approaches to the prostate / Time gap between the beginning of ADT and conduction of mpMRI and PSMA PET scans is >1 month / Radiologically suspicious or pathologically confirmed lymph node involvement (cN+) in mpMRI and/or PSMA PET/CT / Evidence of metastatic disease (cM+) in mpMRI and/or PSMA PET/CT / Evidence of cT4 disease in mpMRI or PSMA PET/CT / PSA >30 ng/ml prior to starting ADT / Expected patient survival <5 years / Bilateral hip prostheses or any other implants/hardware that would introduce substantial CT artefacts / Contraindication to undergo a mpMRI scan / Prostate surgery (TURP or HOLEP) with a significant tissue cavity or prostate surgery (TURP or HOLEP) within the last 6 months prior to randomization / Medical conditions likely to make radiotherapy inadvisable e.g. acute inflammatory bowel disease, hemiplegia or paraplegia / Previous malignancy within the last 2 years (except basal cell carcinoma or squamous cell carcinoma of the skin), or if previous malignancy is expected to significantly compromise 5 year survival / Any other contraindication to external beam radiotherapy (EBRT) to the pelvis / In mpMRI and PSMA PET/CT or PSMA PET/MRI scans no visible tumor / Participation in any other interventional clinical trial within the last 30 days before the start of this trial / Simultaneous participation in other interventional trials which could interfere with this trial; simultaneous participation in registry and diagnostic trials is allowed / Patient without legal capacity who is unable to understand the nature, significance and consequences of the trial; / Known or persistent abuse of medication, drugs or alcohol / Patients expected to have severe set up problems / Dose constraints for organs at risk cannot be adhered to
see Link:

clinicaltrials.gov/NCT06330909

Study Test Center	PI / SC	Phone	E-Mail
UKSH Kiel Radiotherapy	PD Dr. med. Alexander Fabian Frauke Walther-Clausnizer (SC)	0431 500 26507 0431 500 26581	Alexander.Fabian@uksh.de Frauke.Walther-Clausnizer@uksh.de

A Randomized, Double-blind, Placebo-controlled Phase 3 Study of Darolutamide Plus Androgen Deprivation Therapy (ADT) Compared With Placebo Plus ADT in Patients With High-risk Biochemical Recurrence (BCR) of Prostate cancer

Condition: Biochemically Recurrent Prostate cancer
Primary Completion Date: 2027-01-29
Phase: III
Intervention/ Treatment: DRUG: **Darolutamide (BAY1841788, Nubeqa) OTHER: ADT/ Placebo matching Darolutamide**

Inclusion Criteria:
Capable of giving signed informed consent as described which includes compliance with the requirements, restrictions listed in the informed consent form (ICF), and in this protocol. / Male ≥18 years of age at the time of signing the informed consent. / Histologically or cytologically confirmed adenocarcinoma of prostate. / Prostate cancer initially treated by: radical prostatectomy (RP) followed by adjuvant radiotherapy (ART), or salvage radiotherapy (SRT), or RP in participants who are unfit for (or refused) ART or SRT, or primary radiotherapy (RT). / High-risk biochemical recurrence (BCR), defined as Prostate-specific antigen doubling time (PSADT) <12 months calculated using the formula provided by the Sponsor, and PSA ≥0.2 ng/mL after ART or SRT post RP or after RP in participants who are unfit for ART or SRT (local or central values accepted), or PSA ≥2 ng/mL above the nadir after primary RT only (local or central values accepted). / Participants must undergo prostate-specific membrane antigen positron emission tomography/computed tomography (PSMA PET/CT) within the 42-day Screening period using either 18F-DCFPyL (piflufolastat F 18) or 68Ga-PSMA-11 which will be assessed by blinded independent central review (BICR) to identify at least one PSMA PET/CT lesion of prostate cancer. / Serum testosterone ≥150 ng/dL (5.2 nmol/L) (local assessment is allowed whenever central assessment cannot be done). / Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. / Blood counts at screening: Hemoglobin ≥9.0 g/dL (participant must not have received blood transfusion within 7 days prior to sample being taken); Absolute neutrophil count (ANC) ≥1.5x10^9/L (participant must not have received any growth factor within 4 weeks prior to sample being taken); Platelet count ≥100x10^9/L. / Screening values of: Alanine aminotransferase (ALT) ≤1.5 x upper limit of normal (ULN); Aspartate aminotransferase (AST) ≤1.5 x ULN; Total bilirubin (TBL) ≤1.5 ULN, (except participants with a diagnosis of Gilbert's disease); Estimated glomerular filtration rate (eGFR) >40 ml/min/1.73 m^2 calculated by the CKD-EPI formula. / Sexually active male participants must agree to use contraception as detailed in the protocol during the Treatment period and for at least 1 week after the last dose of study treatment, and refrain from donating sperm during this period.
see Link:

clinicaltrials.gov/NCT05794906

Study Test Center	PI / SC	Phone	E-Mail
UKSH Kiel Urology	PD. Dr. med. Severin Rodler	0431 500-24811	Severin.Rodler@uksh.de

Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Prospective, Multi-Center Study to Assess the Diagnostic Performance of [18F]PSMA-1007 PET/CT Imaging in Patients With Newly-Diagnosed High-Risk or Very-High-Risk Prostate cancer

Condition: Prostate cancer
Primary Completion Date: 2025-04
Phase: III
Intervention/ Treatment: DRUG: **[18F]PSMA-1007**

Inclusion Criteria:
The patient (male) is aged 18 years or above. / The patient is able to understand the information presented to him concerning the nature, scope, and consequences of the trial as set out in the information provided to the patient AND has provided written informed consent to participate. / The patient has newly diagnosed, biopsy-proven, clinically localized prostate adenocarcinoma, and curative prostatectomy with extended pelvic lymph node dissection is his preferred course of treatment. / The patient has at least high-risk disease as defined by the NCCN guidelines (version 1.2023). That is, the presence of any one or more of the following: / Overall ISUP grade group 4 or 5, / Clinical category T3a or greater, / Serum PSA level greater than 20 ng/ml. / The patient has undergone conventional imaging (CT or MRI, and bone scan if clinically indicated) to detect the presence of pelvic nodal involvement and bone or visceral metastases within 60 days of the planned PET-CT procedure.
Exclusion Criteria:
Patients for whom radical prostatectomy is not clinically appropriate or the patient is otherwise unlikely to undergo radical prostatectomy with extensive pelvic lymph node dissection. / The patient has received any therapy - be it radiation, surgical or drug therapy - for his prostate cancer. / The patient has any contraindication(s) for and/or known hypersensitivity to any constituent(s) of [18F]PSMA-1007. The patient is not able to have PET-CT scans (for example, because of weight, claustrophobia, or inability to lie still for the duration of the scan). / The patient is closely affiliated to the investigation site; e.g. is a first-degree relative of the investigator. / At the time of screening, the patient is receiving any other investigational agent(s), or he has received any such agent(s) within the previous 30 days, or he is scheduled to receive any such agent(s) in the period up to the planned date for the last study visit. / The patient has previously been enrolled in this trial. / The patient has previously undergone PET imaging with any PSMA-avid product. / The patient has histological evidence of small-cell carcinoma of the prostate. / The patient is clinically unstable or requires emergency treatment. / The patient has any mental condition rendering him incapable of understanding the nature, scope, and consequences of the trial as set out in the information given to the patient.
see Link:

clinicaltrials.gov/NCT06122584

Study Test Center	PI / SC	Phone	E-Mail
Martini Clinic (Hamburg)	Prof. Dr. med. Susanne Klutmann Christiane Görtzen (SC)	0152 228 156 39 040 7410 58091	t.maurer@uke.de c.goertzen@uke.de

Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Phase Ib/II Trial of Pembrolizumab (MK-3475) Combination Therapies in Metastatic Castration-Resistant Prostate cancer (mCRPC)

Condition: Metastatic Castration-Resistant Prostate cancer
Primary Completion Date: 2027-10-22
Phase: I/II
Intervention/ Treatment: DRUG: **Olaparib 400 mg/ Docetaxel 75 mg/m^2/ Prednisone 5 mg/ Enzalutamide 160 mg/ Olaparib 300 mg/ Abiraterone acetate 1000 mg/ Lenvatinib/ Carboplatin/ Etoposide**, BIOLOGICAL: **Pembrolizumab/Vibostolimab coformulation/ Pembrolizumab 200 mg/ Belzutifan 120mg**
OTHER: **Dexamethasone 8 mg**

Inclusion Criteria:

For Cohorts A, B, C, D, E, G, J: Has histologically- or cytologically-confirmed adenocarcinoma of the prostate without small cell histology / **For Cohorts F, H, I:** Has t-NE or de novo metastatic prostate cancer defined by ≥1% neuroendocrine cells that are located in discrete regions of a recent biopsy specimen from a metastasis as determined by the investigational site and confirmed by central histology review prior to enrollment. Epstein criteria of neuroendocrine differentiation in prostate cancer is used for eligibility. Specimens must have one of the morphologies of Small cell carcinoma or Large cell neuroendocrine carcinoma (LCNEC) or Mixed (small or large cell) NE carcinoma - acinar adenocarcinoma with positive IHC confirmed by central pathology review / Is able to provide tumor tissue from a site not previously irradiated as follows: Cohorts A, E, G and J: must provide a core or excisional biopsy from soft tissue or bone biopsy within 1 year of screening and after developing mCRPC; Cohort B: must provide an archival tumor tissue sample or tumor tissue from a newly obtained core or excisional biopsy from soft tissue if the lesion is clinically accessible; Cohorts C and D with soft tissue disease: must provide a core or excisional biopsy from a soft tissue lesion if clinically accessible within 1 year of screening and after developing mCRPC and an archival specimen if available; and Cohorts F, H, and I must provide a core or excisional biopsy from soft tissue or a bone biopsy. For de novo metastatic neuroendocrine prostate participants, biopsies must be performed within 1 year of screening. Participants with bone metastasis only must provide an archival tumor tissue specimen / Has prostate cancer progression within 6 months prior to screening, as determined by the investigator, by means of one of the following: PSA progression as defined by a minimum of 2 rising PSA levels with an interval of ≥1 week between each assessment where the PSA value at screening should be ≥2 ng/mL; radiographic disease progression in soft tissue based on Response Evaluation Criteria In Solid Tumors Version 1.1 criteria with or without PSA progression; radiographic disease progression in bone defined as the appearance of 2 or more new bone lesions on bone scan with or without PSA progression. Participants with de novo neuroendocrine prostate cancer will not need to provide evidence of progression within 6 months / Has ongoing androgen deprivation with serum testosterone <50 ng/dL (<2.0 nM). Treatment with luteinizing hormone-releasing hormone agonists or antagonists for all cohorts must have been initiated ≥4 weeks prior to first dose of study therapy and must be continued throughout the study. Participants with de novo metastatic NE prostate cancer will not be required to have been previously treated with androgen deprivation therapy (ADT). ADT must be started in these participants by the time of treatment allocation/randomization / Participants receiving bone resorptive therapy (including, but not limited to bisphosphonate or receptor activator of nuclear factor kappa-β ligand inhibitor) must be on stable doses for ≥4 weeks prior to first dose of study therapy / Must be abstinent from heterosexual intercourse, refrain from donating sperm, or agree to use contraception (unless confirmed to be azoospermic) during the intervention period starting with the first dose of study therapy. The length of time required to continue contraception after the last dose of study intervention for each study intervention is as follows: 7 days for abiraterone acetate and lenvatinib; 30 days for enzalutamide; and 95 days for olaparib, docetaxel, and carboplatin/etoposide. No contraception measures are required during and after the intervention period for pembrolizumab/vibostolimab coformulation / Has a performance status of 0, 1, or 2 on the Eastern Cooperative Oncology Group (ECOG) Performance Scale for Cohorts A and C and a performance status of 0 or 1 for Cohorts B, D, E, F, G, H, I and J within 10 days of study start / **For Cohort A:** Has received docetaxel for mCRPC. Prior treatment with 1 other chemotherapy for mCRPC is allowed. Up to 2 second-generation hormonal manipulations (e.g., abiraterone acetate and/or enzalutamide) are allowed. Prior docetaxel for metastatic hormone-sensitive prostate cancer is allowed if ≥4 weeks have elapsed from the last dose of docetaxel prior to day 1 of Cycle 1 / **For Cohort B:** Has received prior treatment with either abiraterone acetate or enzalutamide (but not both) in the prechemotherapy mCRPC state. Participants in Cohort B must have received at least 4 weeks of either abiraterone or enzalutamide treatment (but not both) who failed treatment or became intolerant of the drug / **For Cohort C**: Has received prior treatment with abiraterone acetate in the pre-chemotherapy mCRPC state without prior enzalutamide. Participants in Cohort C must have received at least 4 weeks of abiraterone treatment who failed treatment or become intolerant of the drug. Participants who received abiraterone acetate in the hormone-sensitive state will not be eligible / **For Cohort D:** Has not received chemotherapy for mCRPC and has either not had prior second generation hormonal manipulation for mCRPC OR has previously been treated with enzalutamide for mCRPC and failed treatment or has become intolerant of the drug. Prior docetaxel for metastatic hormone-sensitive prostate cancer is allowed if ≥4 weeks have elapsed from the last dose of docetaxel. Prior treatment with abiraterone acetate in the hormone-sensitive metastatic setting is allowed as long as there was no progression on this agent and abiraterone acetate was not discontinued due to adverse events (AEs)

For Cohorts E, G and J: Has received docetaxel for mCRPC. Prior treatment with 1 other chemotherapy for mCRPC is allowed. Up to 2 second-generation hormonal manipulations (eg, abiraterone acetate, enzalutamide, apalutamide, darolutamide or other next-generation hormonal agents [NHA]) are allowed. Participants who received prior ketoconazole for metastatic disease may be enrolled. If docetaxel chemotherapy is used more than once (eg, once for metastatic hormone-sensitive and once for mCRPC), it will be considered as 1 therapy. Prior docetaxel for metastatic hormone-sensitive prostate cancer (mHSPC) is allowed if ≥4 weeks have elapsed from the last dose of docetaxel prior to Day 1 of Cycle 1

For Cohort F, H, and I: Participants must have received prior treatment with androgen deprivation therapy (ADT) for metastatic disease. Prior treatment with up to a total of 2 chemotherapies for mCRPC is allowed, as well as up to 2 second-generation hormonal manipulations for mCRPC. Participants who received prior ketoconazole for metastatic disease may be enrolled. Docetaxel for mHSPC is allowed in addition to docetaxel for mCRPC. If docetaxel chemotherapy is used more than once (eg, once for metastatic hormone-sensitive and once for mCRPC), it will be considered as 1 therapy

see Link:

clinicaltrials.gov/NCT02861573

Study Test Center	PI / SC	Phone	E-Mail
UKE Medical Oncology	Prof. Dr. med. Gunhild von Amsberg	0152-228 39 570	g.von-amsberg@uke.de

Universitäres Cancer Center HAMBURG

Universitätsklinikum Hamburg-Eppendorf

A Phase 3 Randomized, Open-label Study of MK-5684 Versus Alternative Abiraterone Acetate or Enzalutamide in Participants With Metastatic Castration-resistant Prostate cancer (mCRPC) Previously Treated With Next-generation Hormonal Agent (NHA) and Taxane-based Chemotherapy

Condition: Prostatic cancer Metastatic
Primary Completion Date: 2028-08-02
Phase: III
Intervention/ Treatment: DRUG: **Opevesostat/ Abiraterone acetate/ Enzalutamide/ Hydrocortisone/ Fludrocortisone acetate/ Prednisone/ Dexamethasone**

Inclusion Criteria:
Has histologically- or cytologically-confirmed adenocarcinoma of the prostate without small cell histology / Has prostate cancer progression while on androgen deprivation therapy (or post bilateral orchiectomy) within 6 months before Screening / Has current evidence of metastatic disease documented by either bone lesions on bone scan and/or soft tissue disease by computed tomography/magnetic resonance imaging (CT/MRI) / Has disease that progressed during or after treatment with 1 novel hormonal agent (NHA) / Has received 1 but no more than 2 taxane-based chemotherapy regimens for metastatic castration-resistant prostate cancer (mCRPC) and has had progressive disease (PD) during or after treatment / Has ongoing androgen deprivation with serum testosterone <50 ng/dL (<1.7 nM)
Has provided tumor tissue from a fresh core or excisional biopsy from soft tissue not previously irradiated / Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 assessed within 7 days of randomization / Has had prior treatment with PARPi or were deemed ineligible to receive treatment by the investigator or have refused PARPi treatment / Has received prior 177Lu-PSMA-617 or were deemed ineligible to receive 177Lu-PSMA-617 treatment by the investigator or refused 177Lu-PSMA-617 treatment / Participants who have not received cabazitaxel can be enrolled if they are ineligible for cabazitaxel treatment as determined by the investigator or have refused treatment / If participant received first generation anti-androgen therapy before screening, the participant has evidence of disease progression >4 weeks since the last flutamide treatment and >6 weeks since the last bicalutamide or nilutamide treatment / Participants receiving bone resorptive therapy (including, but not limited to, bisphosphonate or denosumab) must have been on stable doses for ≥ 4 weeks before the date of randomization / articipants with human immunodeficiency virus (HIV) infection must have well controlled HIV on antiretroviral therapy (ART) / Participants who are hepatitis B surface antigen (HBsAg) positive are eligible if they have received hepatitis B virus (HBV) antiviral therapy for at least 4 weeks and have undetectable HBV viral load before randomization / Participants with history of hepatitis C virus (HCV) infection are eligible if HCV viral load is undetectable at Screening. / Participants who can produce sperm must agree to the following during the study treatment period and for at least 7 days after the last dose of opevesostat, for at least 30 days after the last dose of abiraterone acetate, and for at least 3 months after the last dose of enzalutamide: EITHER be abstinent OR must agree to use male condom
see Link:

clinicaltrials.gov/NCT06136624

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Early Prostate cancer Recurrence With PSMA PET Positive Unilateral Pelvic Lesion(s): is One-sided Salvage Extended Lymph Node Dissection Enough

Condition: Prostate cancer
Estimated Completion Date: 2025-12-31
Phase: N/A
Intervention/ Treatment: PROCEDURE: **Salvage Lymphnode dissection**

Inclusion Criteria:
Patients in good general condition with life expectancy> 10 years / Hormone-sensitive prostate cancer recurrence after radical prostatectomy (patients with status post salvage prostatectomy may be included; salvage radiotherapy for prostate fossa and / or pelvic lymph drainage after radical prostatectomy is not an exclusion criterion) / Unilateral detection of ≤ 3 PSMA PET positive lymph node metastases in the pelvis (up ot origin of the inferior mesenteric artery) / PSA at the time of PSMA PET imaging <4 ng / ml

Exclusion Criteria:
Contraindication for surgery or bilateral salvage lymph node dissection / Suspected prostate cancer recurrence in the prostate fossa (local recurrence) or extrapelvic metastasis on PSMA PET imaging / Date of PSMA PET examination > 4 months prior to salvage lymph node dissection / Hormone therapy within 6 months prior to study enrollment

see Link:

clinicaltrials.gov/NCT04271579

Study Test Center	PI / SC	Phone	E-Mail
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Active Surveillance Plus (AS+): Local Tumor Control With High-intensity Focused Ultrasound (HIFU) in Patients With Localized Prostate cancer

Condition: Prostate cancer
Estimated Completion Date: 2030-09
Phase: N(A
Intervention/ Treatment: PROCEDURE: **high-intensity focused ultrasound, HIFU**

Inclusion Criteria:
Age 55-80 years / Life expectancy >10 years / Gleason-score:patients <75 years: Gleason score < 8 / patients 75-80 years: Gleason <9 / TNM-stage: clinical/ radiological stage <T2c (localized), rN0 and rM0 PSA < 15 / PSA > 15 should be counseled with caution (does not apply to patients >75 years) / **Risk group:** d'Amico intermediary risk group, open for high risk patients age >75 years

Exclusion Criteria:
Previous treatment / Previous treatment of the primary cancer within the prostate / Previous hormone treatment for prostate cancer within 6 months before trial / Previous radiation to pelvis / Acute urinary tract infection / For patients <75 years: >5% chance of lymph node metastases calculated by the updated prostate cancer staging nomogram (Partin tables) (30) / Radiological imaging: PI-RADS score <3, clinical significant cancer is equivocal / Extracapsular extension or seminal vesicle invasion / Lymph node or bone metastasis / > 2 MRI detected tumors validated by systematic or MRI-guided biopsies Contraindications for MRI

see Link:

clinicaltrials.gov/NCT04271579

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Phase 1b, Open-Label, Multicenter Study Evaluating the Safety, Tolerability, and Feasibility of Neoadjuvant Xaluritamig Therapy Prior to Radical Prostatectomy in Subjects With Newly Diagnosed Localized Intermediate or High-Risk Prostate Cancer

Condition: Prostate cancer
Estimated Completion Date: 2026-06-21
Phase: I
Intervention/ Treatment: DRUG: **Xaluritamig**

Inclusion Criteria:
Subjects are eligible to be included in the study only if all the following criteria apply: / Subjects planned to undergo radical prostatectomy. / Histologically or cytologically confirmed adenocarcinoma of the prostate at initial biopsy, without neuroendocrine differentiation, signet cell, or small cell features. Intermediate- or high-risk localized prostate cancer, defined as:Gleason score of 4+3 or higher AND iPSA >10 OR / Clinically advanced (cT3) on MRI imaging obtained within 3 months prior to screening AND/OR / Positive locoregional lymph nodes as detected by PSMA-PET scans OR equal or ≤ 5 local lymph nodes on MRI can be enrolled. / Subjects must have undergone a gallium-68 prostate-specific membrane antigen (68Ga-PSMA-11) or a piflufolastat F 18 PET (CT or MRI) scan within 3 months prior to screening as part of the SOC. / Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1.

Exclusion Criteria:
Subjects are excluded from the study if any of the following criteria apply: / Prior treatment for subject's prostate cancer. / Any evidence of metastases outside of the surgical resection field identified by conventional imaging or PSMA-PET scans. / Confirmed history or current autoimmune disease or other diseases resulting in permanent immunosuppression or requiring permanent immunosuppressive therapy. / Subject with symptoms and/or clinical signs and/or radiographic signs that indicate an acute and/or uncontrolled active systemic infection within 7 days prior to the first dose of study treatment: / Subject has known active infection requiring antibiotic treatment. Upon completion of antibiotics and resolution of symptoms, the subject may be considered eligible for the study from an infection standpoint. History of arterial or venous thrombosis or other diseases requiring permanent anticoagulation (eg, stroke, transient ischemic attack, pulmonary embolism, or deep vein thrombosis): / Patients requiring anticoagulation due to atrial fibrillation may be allowed if they can safely stop the anticoagulation for the perisurgical timeframe. / Myocardial infarction and/or symptomatic congestive heart failure (New York Heart Association ≥ class II) within 12 months of first dose of xaluritamig with the exception of ischemia or non-ST segment elevation myocardial infarction controlled with stent placement more than 6 months prior to first dose of xaluritamig. / Requirement for chronic systemic corticosteroid therapy / Currently receiving treatment in another investigational device or drug study, or less than 4 weeks (since ending treatment on another investigational device or drug study[ies]). Other investigational procedures and participation in observational research studies while participating in this study are excluded with the exception of investigational scans.
see Link:

clinicaltrials.gov/NCT06613100

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Phase 1/2 Umbrella Substudy of MK-5684-U01 Master Protocol to Evaluate the Safety and Efficacy of MK-5684-based Treatment Combinations or MK-5684 Alone in Participants With Metastatic Castration-resistant Prostate Cancer (mCRPC)

Condition: Prostatic Neoplasms, Castration-Resistant
Estimated Completion Date: 2028-03-31
Phase: I/II
Intervention/ Treatment: DRUG: **Opevesostat/ Olaparib/ Docetaxel/ Cabazitaxel/ Fludrocortisone acetate/ Dexamethasone/ Prednisone**

Inclusion Criteria:
The main inclusion criteria include but are not limited to the following: / Histologically or cytologically confirmed diagnosis of adenocarcinoma of the prostate without small cell histology. / Prostate cancer progression and received androgen deprivation therapy (ADT) or post bilateral orchiectomy within 6 months before screening. / Evidence of disease progression from either, >4 weeks from last flutamide treatment, or >6 weeks from last bicalutamide or nilutamide treatment, if receiving first generation anti-androgen therapy as last treatment therapy. / Current evidence of metastatic disease. / Prior treatment with 1 to 2 novel hormonal agent(s) (NHA) for non-metastatic, or metastatic, hormone-sensitive prostate cancer or castration-resistant prostate cancer and have disease progression during or after treatment. Treatment with bone resorptive therapy (including, but not limited to, bisphosphonate or denosumab) must have been on stable doses for >4 weeks before randomization. / Participants who experienced adverse events (AEs) due to previous anticancer therapies must have recovered to <Grade 1 or baseline. / Human immunodeficiency virus (HIV)-infected participants must have well controlled HIV on antiretroviral therapy. / Participants who are Hepatitis B surface antigen (HBsAg) positive are eligible if they have received Hepatitis B Virus (HBV) antiviral therapy for at least 4 weeks, and have undetectable HBV viral load. / Participants with a history of Hepatitis C virus (HCV) infection are eligible if HCV viral load is undetectable.
see Link:

clinicaltrials.gov/NCT06353386

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Phase 3, randomized, double blind,Placebo controlled study pf PF-06821497 (Mevremetostat) with Enzalutamide in metatstatic castration resistant Prostate Cancer

Condition: Metastatic Castration-Resistant Prostate Cancer
Completion Date: 2028-11-30
Phase: III
Intervention/ Treatment: DRUG: **PF-06821497/ Enzalutamide/ Placebo**

Inclusion Criteria:
Male participants aged ≥18 years (or the minimum age of consent in accordance with local regulations) at screening. / Histologically or cytologically confirmed adenocarcinoma of the prostate without small cell features. / Metastatic disease in bone documented on bone scan, or in soft tissue documented on CT/MRI scan. / Surgically or medically castrated, with serum testosterone ≤50 ng/dL (≤1.73 nmol/L) at screening. / Metastatic disease in bone documented on bone scan, or in soft tissue documented on CT/MRI scan. / Progressive disease in the setting of medical or surgical castration. / Prior to randomization, there must be resolution of acute effects of any prior therapy to either baseline severity or CTCAE Grade ≤1. / ECOG performance status 0 or 1, with a life expectancy of ≥12 months as assessed by the investigator.

Exclusion Criteria:
Any medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may increase the risk of study participation or, in the investigator's judgment, make the participant inappropriate for the study. / Clinically significant cardiovascular disease. / Known or suspected brain metastasis or active leptomeningeal disease. / Participants must be treatment naïve at the mCRPC stage, eg, participants cannot have received any cytotoxic chemotherapy with the following exceptions: Treatment with first-generation antiandrogen (ADT) agents and. Docetaxel treatment is allowed for mCSPC. / revious administration with an investigational product (drug or vaccine) within 30 days. / Current use or anticipated need for drugs that are known strong CYP3A4/5 inhibitors and inducers (with exception of enzalutamide as part of this study). / Major surgery or palliative localized radiation therapy within 14 days before randomization. / Inadequate organ function.

see Link:

clinicaltrials.gov/NCT06629779

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A phase 3, randomized, open-label Study of PF-06821497 (Mevrometostat) in combination with Enzalutamide compared with Enzalutamide or Docetaxelin participants with metatstatic castration resistant Prostate cancer previously treated with Abiraterone acetate

Condition: Metastatic Castration-Resistant Prostate Cancer (mCRPC)
Completion Date: 2028-10-29
Phase: III
Intervention/ Treatment: DRUG: **PF-06821497/ Enzalutamide/ Docetaxel**

Inclusion Criteria:
Histologically or cytologically confirmed adenocarcinoma of the prostate without small cell features. / Metastatic disease in bone documented on bone scan, or in soft tissue documented on CT/MRI scan. / Progressive disease in the setting of surgical or medical castration. / Eastern Cooperate Oncology Group (ECOG) performance status 0 - 2, with life expectancy of at least 6 months as assessed by the investigator.

Exclusion Criteria:
Any medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may make the participant. inappropriate for the study. / Clinically significant cardiovascular disease. / Known or suspected brain metastasis or active leptomeningeal disease or clinically significant history of seizure. / Prior treatment for prostate cancer at any stage with any cytotoxic chemotherapy, radioligand therapy, androgen receptor signaling inhibitors (ARSi) including enzalutamide, apalutamide, darolutamide, poly ADP-ribose polymerase (PARP) monotherapy or other systemic anti-cancer treatment. with the following exceptions: / Treatment with first-generation antiandrogen agents, if discontinued prior to randomization / Docetaxel treatment is allowed for mCSPC, as long as no signs of failure, or disease progression occurred during treatment or within 3 months of treatment completion. / Previous administration with an investigational product within 30 days or 5 half-lives preceding the first dose of study intervention (whichever is shorter). / Inadequate organ function.

see Link:

clinicaltrials.gov/NCT06551324

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Hypofractionated Radiosurgery for Localised Prostate Cancer (HYPOSTAT-III)

Condition: Prostate Cancer
Completion Date: 2028-12-31
Phase: N/A
Intervention/ Treatment: RADIATION: **Hypofractionated Radiosurgery**

Inclusion Criteria:
Localised, histopathologically confirmed Prostate Cancer (cT1-T2c N0 M0) / Gleason-grade ≤7, ISUP Grade Group 1-3 / Guideline-based staging / Age ≥ 18 years / PSA < 20 ng/ml / Volume of the prostate < 80 cm³ / IPSS-Score ≤ 12 / Written informed consent
Exclusion Criteria:
Exclusion Criteria:
History of prior pelvic radiotherapy / Previous transurethral resection, laser enucleation or prostate ablation / Contraindication to MRI or Fiducial marker implantation (e.g. gold allergy) / Relevant comorbidity thought to adversely affect treatment compliance / Legal incapacity or lack of informed consent
see Link:

clinicaltrials.gov/NCT06914544

Study Test Center	PI / SC	Phone	E-Mail
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Neuroendocrine tumors / carcinomas

continue...

Contact at UCC Hamburg
Dr. med. Thorben W. Fründt, Tel.: 040 7410-18056

Currently no study options

continue...

Breast cancer

continue...

Contact at UCC Hamburg
Prof. Dr. med. Volkmar Müller, Tel.: 040 7410-52510

Neoadjuvant dynamic marker-matched personalized therapy comparing sacituzumab govitecan and sacituzumab govitecan + pembrolizumab in triple-negative low-risk early breast cancer

Condition: Triple Negative Breast cancer
Primary Completion Date: 2029-09
Phase: II
Intervention/ Treatment: DRUG: **Sacituzumab govitecan/ Pembrolizumab**

Inclusion Criteria:
ER + PR negative or low positive (≤10% positive cells in IHC), and HER2 negative (i.e., IHC 0 - 1+ or IHC 2+ with FISH negative) breast cancer / All patients, independent from gender / ≥18 years at diagnosis / Histologically confirmed unilateral, primary invasive carcinoma of the breast Note: bilateral, multicentric, or multifocal carcinoma may be included, if there is a clear target lesion, that is subject to treatment decisions and solely evaluated and documented for study purposes. / Clinical stage I: cT1a-c, cN0 (clinical stage II only, if patient does not qualify for neoadjuvant polychemotherapy+PEM, e.g., elderly population, per investigator´s decision) / No clinical evidence for distant metastasis (M0) / Tumour block available for central pathology review / Performance Status ECOG ≤ 1 or KI ≥ 80%
Negative pregnancy test (urine or serum) within 7 days prior to registration in premenopausal patients / Written informed consent prior to beginning specific protocol procedures, including expected cooperation of the patients for the treatment and follow-up, must be obtained and documented according to the local regulatory requirements / The patient must be willing and able to comply with the requirements and restrictions in this protocol and accessible for treatment and follow-up / **Laboratory requirements**:Leucocytes ≥3.5 109/L,Neutrophils > 1.5 109/L, Platelets ≥100 109/L, Haemoglobin ≥10 g/dL, AP < 5.0 ULN, AST ≤2.5 x ULN, ALT ≤2.5 x ULN, Total bilirubin ≤1 x ULN, Creatinine ≤1.5 × ULN OR clearance ≥30 mL/min for participant with creatinine levels >1.5 × institutional ULN /
Clinical assessments: • LVEF within normal limits of each institution, measured by echocardiography and normal ECG (within 42 days prior to treatment) / The following age-specific requirements apply: / Women aged <50 years will be considered post-menopausal if they have been amenorrhoeic for 12 months or more following cessation of exogenous hormonal treatments and if they have luteinizing hormone (LH) and follicle-stimulating hormone (FSH) levels in the post-menopausal range for the site. / Women aged ≥ 50 years will be considered post-menopausal if they have been amenorrhoeic for 12 months or more following cessation of all exogenous hormonal treatments. / Females on hormone replacement therapy (HRT) and whose menopausal status is in doubt will be required to use one of the contraception methods outlined for women of child-bearing potential if they wish to continue their HRT during the study. Otherwise, they must discontinue HRT to allow confirmation of post-menopausal status prior to randomization/study enrolment. For most forms of HRT, at least 2-4 weeks will elapse between the cessation of therapy and the blood draw; this interval depends on the type and dosage of HRT. Following confirmation of their post-menopausal status, they can resume use of HRT during the study without use of a contraceptive method. / Female patients of childbearing potential who are sexually active with a non-sterilized male partner must use at least one highly effective method of contraception, presented in Table 1 (see Section 4.4.2), from the time of screening and must agree to continue using such precautions for 7 months after the last dose of IMP. Not all methods of contraception are highly effective. Female patients must refrain from breastfeeding while on study and for 7 months after the last dose of IMP. Complete heterosexual abstinence for the duration of the study and drug washout period is an acceptable contraceptive method if it is line with the patient's usual lifestyle (consideration must be made to the duration of the clinical trial); however, periodic, or occasional abstinence, the rhythm method, and the withdrawal method are not acceptable. / Female patients must not donate, or retrieve for their own use, ova from the time of randomisation and throughout the study treatment period, and for at least 7 months after the final study drug administration. They should refrain from breastfeeding throughout this time. Preservation of ova may be considered prior to enrolment in this study. A male participant must agree to use a contraception as detailed in Appendix C of this protocol during the treatment period and for at least 7 months after the last dose of study treatment and refrain from donating sperm during this period.
see Link:

clinicaltrials.gov/NCT06081244

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Neoadjuvant dynamic marker-matched personalized therapy comparing sacituzumab govitecan and sacituzumab govitecan + pembrolizumab in triple-negative low-risk early breast cancer

Condition: Breast cancer
Primary Completion Date: 2026-12
Phase: III
Intervention/ Treatment: BIOLOGICAL: **Placebo/ GLSI-100**

Inclusion Criteria:
HLA-A*02-positive, unless being enrolled in the third non-HLA-A*02 arm / Histologically confirmed diagnosis of HER2/neu positive primary breast cancer for all tumors biopsied (multifocal, multicentric, or synchronous contralateral disease) / Completion of both neoadjuvant and adjuvant trastuzumab-based standard of care breast cancer therapy / Stage I, II, or III at presentation with pathologic evidence of residual invasive carcinoma in the breast or axillary lymph nodes (residual disease) at surgery following completion of neoadjuvant therapy -OR- Stage III at presentation with pathologic complete response (pCR) at surgery following completion of neoadjuvant therapy / The subject can begin study therapy within one year of completion of adjuvant trastuzumab-based therapy and any other standard therapies, but, study therapy can be administered concurrently with endocrine therapy. / No clinical evidence of residual or persistent breast cancer per treating physician assessment / ECOG 0-2 / Adequate organ function / Negative pregnancy test or evidence of post-menopausal status / If of childbearing potential, willing to use a form of highly effective contraception / Subject must both reside in and have been treated for their cancer in the country in which the clinical site is located.

Exclusion Criteria:
Stage IV cancer or metastatic breast cancer at any time / Inflammatory breast cancer / Receiving other investigational agents / Receiving chemotherapy / Requiring long-term systemic treatment with corticosteroids or other immunosuppressive therapy / History of immunodeficiency or active autoimmune disease / A history of serious allergic reactions, including anaphylaxis, to human granulocyte-macrophage colony-stimulating factors such as sargramostim, yeast-derived products, or any component of the investigational product / Other malignancies except adequately treated in situ carcinoma of the cervix or basal cell or squamous cell carcinoma of the skin / Active infection / Known HIV infection with a detectable viral load within 6 months of the anticipated start of treatment. Note: Subjects on effective antiretroviral therapy with an undetectable viral load within 6 months of the anticipated start of treatment are eligible for this trial.
see Link:

clinicaltrials.gov/NCT05232916

Study Test Center	PI / SC	Phone	E-Mail
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Phase II neoadjuvant study evaluating capivasertib plus fulvestrant vs fulvestrant in patients with primary high-risk lobular breast cancer

Condition: Breast cancer/ Neoplasms
Primary Completion Date: 2026-12
Phase: II
Intervention/ Treatment: DRUG: **Capivasertib + Fulvestrant/ Fulvestrant**

Inclusion Criteria:
Written informed consent prior to beginning specific protocol procedures, including expected cooperation of the patients for the treatment and followup, and documented according to the local regulatory requirements. / The patient must be accessible for scheduled visits, treatment, and follow-up. / Normal cardiac function must be confirmed according to local guidelines. / **Laboratory requirements:** Hematology • Absolute neutrophil count (ANC) ≥1.5 x 109 / L • Platelets ≥100 x 109 / L • Hemoglobin ≥10 g/dL (≥6.2 mmol/L) Hepatic function • Total bilirubin <1.25x ULN • AST and ALT <=1.5x ULN • Alkaline phosphatase <=2.5x ULN Glucose Metabolism • HbA1c <8.0% (63.9 mmol/mol) Renal Function • Creatinine <1.25x ULN or creatinine clearance ≥50 ml/min (if creatinine is above ULN according to Cockroft-Gault). / Complete staging work-up prior to the initiation of neoadjuvant therapy as per standard recommendations. / Postmenopausal women with age at diagnosis ≥ 18 years. Postmenopausal status is defined as: • Age ≥ 60 years • Age <60 years and amenorrhea for at least 12 continuous months with no identified cause other than menopause / Bilateral oophorectomy Negative pregnancy test (urine or serum) within 14 days prior to randomization for all postmenopausal women 50 years of age or younger without bilateral oophorectomy / Unilateral or bilateral primary untreated lobular invasive carcinoma of the breast. In case of multifocal, multicentric or bilateral breast cancer, all biopsied / Willingness and ability to provide archived formalin fixed paraffin embedded (FFPE) tissue block from core biopsy before the start of neoadjuvant therapy. / Centrally confirmed HER2-negative (IHC score 0-1+, or 2+ and ISH negative according to ASCO/CAP guideline) and HR-positive (≥10% positive stained cells) disease, assessed on the core of diagnostic biopsy. Ki67% >8% is required. In case of bilateral breast cancer, HER2-negative, HR-positive and lobular histology status has to be confirmed for both sides. / **P**atients with invasive lobular breast cancer at high risk for recurrence defined as cT1c and clinical nodal involvement (cN+) or ≥ cT2 disease (irrespective of nodal involvement). / No clinical evidence of distant metastases. / Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0 or 1. / Estimated life expectancy of at least 5 years irrespective of the diagnosis of breast cancer.
see Link:

euclinivaltrials.eu:2023-509292-17-00

Study Test Center	PI / SC	Phone	E-Mail
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Study of Sacituzumab Govitecan-hziy and Pembrolizumab Versus Treatment of Physician's Choice in Patients With Triple Negative Breast Cancer Who Have Residual Invasive Disease After Surgery and Neoadjuvant Therapy

Condition: Triple Negative Breast cancer
Primary Completion Date: 2027-06
Phase: III
Intervention/ Treatment: DRUG: **Sacituzumab govitecan-hziy (SG)/ Pembrolizumab/ Capecitabine**

Inclusion Criteria:
Age > 18 years, with residual invasive triple negative breast cancer (TNBC) in the breast or lymph nodes after neoadjuvant therapy and surgery: / TNBC criteria for the study is defined as estrogen receptor (ER) and progesterone receptor (PR) ≤ 10%, human epidermal growth factor receptor 2 (HER2)-negative per American Society of Clinical Oncology and College of American Pathologists (ASCO/CAP) guidelines (immunohistochemistry (IHC) and/or in situ hybridization (ISH)). / Adequate excision and surgical removal of all clinically evident of disease in the breast and/or lymph nodes and have adequately recovered from surgery. / Submission of both pre-neoadjuvant treatment diagnostic biopsy and resected residual invasive disease tissue. / Eastern Cooperative Oncology Group (ECOG) performance status 0-1. / Individuals must have received appropriate radiotherapy and have recovered prior to starting study treatment. / Adequate organ function.

Exclusion Criteria:
Stage IV (metastatic) breast cancer as well as history of any prior (ipsi- or contralateral) invasive breast cancer. / Prior treatment with another stimulatory or coinhibitory T-cell receptor agent (eg, cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4), OX-40, cluster of differentiation 137 (CD137), prior treatment with any HER2-directed agent, prior endocrine therapy for > 4 weeks or planned concurrent endocrine therapy while receiving on-study treatment. / Evidence of recurrent disease following preoperative therapy and surgery. / Prior treatment with topoisomerase 1 inhibitors or antibody-drug conjugates (ADCs) containing a topoisomerase inhibitor. / Individuals with germline breast cancer gene (BRCA) mutations. / Myocardial infarction or unstable angina pectoris within 6 months of enrollment or history of serious ventricular arrhythmia (ie, ventricular tachycardia or ventricular fibrillation), high-grade atrioventricular block, or other cardiac arrhythmias or Left ventricular ejection fraction (LVEF) of < 50% Active serious infections requiring anti-microbial therapy. /
Note: Other protocol defined Inclusion/Exclusion criteria may apply.
see Link:

clinicaltrials.gov/NCT05633654

Study Test Center	PI / SC	Phone	E-Mail
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Universitätsklinikum Hamburg-Eppendorf

Saruparib (AZD5305) plus camizestrant versus CDK4/6 inhibitor plus endocrine therapy or plus camizestrant in HR-positive, HER2-negative (IHC 0, 1+, 2+/ ISH not amplified), BRCA1, BRCA2 or PALB2m advanced breast cancer

Condition: Advanced Breast cancer
Primary Completion Date: 2029-03-30
Phase: III
Intervention/ Treatment: DRUG: **Saruparib (AZD5305)/ Camizestrant/ Abemaciclib/ Ribociclib/ Palbociclib/ Fulvestrant/ Letrozole/ Anastrozole/ Exemestane**

Inclusion Criteria:
Adult females, pre/peri-menopausal and/or post-menopausal, and adult males / Histologically or cytologically documented diagnosis of HR-positive, HER2-negative breast cancer / Advanced breast cancer with either locally advanced disease not amenable to curative treatment or metastatic disease / ECOG performance status of 0 or 1 with no deterioration over the previous 2 weeks / FFPE tumour tissue from each participant / Documented germline tumour loss of function mutation in BRCA1, BRCA2, or PALB2 / Adequate organ and marrow function
Exclusion Criteria:
see Link

clinicaltrials.gov/NCT06380751

Study Test Center	PI / SC	Phone	E-Mail
Jerusalem Krankenhaus Breast Center	Prof. Dr. med. Christian Schem Silke Kassner /SN)	040-44190- 69/670	schem@mammazentrum.eu kassner@mammazentrum.eu

Preoperative radiotherapy versus postoperative radiotherapy after neoadjuvant chemotherapy for high-risk breast cancer: a prospective, randomized, international multicenter phase III trial

Condition: Breast Cancer
Primary Completion Date: 2028-03-31
Phase III
Intervention/ Treatment: RADIATION: **preoperative radiotherapy,/ postoperative radiotherapy**

Inclusion
Histologically proven invasive, unilateral breast cancer / Indication for radiotherapy / Indication for neoadjuvant chemotherapy (+/- antibody treatment or other targeted therapies) in accordance with national and international guidelines / Female / Informed consent for the trial signed by the patient / Hormone receptor and HER2 status: no restrictions / All grades G1-G3 / Age ≥ 18 years at the time of informed consent / Performance status ≤ 2 / No pre-existing conditions that prohibit therapy

Exclusion Criteria:
Neoadjuvant treatment solely with endocrine therapy / Bilateral breast cancer / Pregnancy or lactation / Prior radiotherapy of the thorax / Connective tissue disease, including rheumatoid arthritis and thromboangiitis obliterans / Pre-existing symptomatic chronic lung disease (fibrosis, pneumoconiosis, adult-onset allergies, such as farmer's lung, severe lung emphysema, COPD °III) / Cardiac comorbidities: symptomatic coronary heart disease, prior heart attack, heart failure NYHA ≥II or AHA ≥C, pacemaker, and/or implanted defibrillatorv / Malignoma except basalioma or in-situ-carcinomas in complete response / Distant metastasis / Plexopathies of the arm of the treated side / Stiffness of the shoulder of the arm of the side of the breast cancer of any origin (e.g. following a road accident) / Lymph edema ≥°II of the arm at the side of the breast cancer / Other medical conditions that prohibit the neoadjuvant radiotherapy (i.e. Expected non-compliance, etc.) / Male patients
Patients who have previously been assessed for chemotherapy response
see Link:

clinicaltrials.gov/NCT04261244

Study Test Center	PI / SC	Phone	E-Mail
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Combination of Abemaciclib and Endocrine Therapy in Hormone Receptor Positive HER2 Negative Locally Advanced or Metastatic Breast Cancer With Focus on Digital Side Effect Management. The MINERVA Trial - A Phase IV Trial

Condition: Hormone Receptor-positive Metastatic Breast Cancer/ HER2-negative Metastatic Breast Cancer
Primary Completion Date: 2029-04
Phase: IV
Intervention/ Treatment: DRUG: **Abemaciclib + Aromatase Inhibitor/ Abemaciclib + Fulvestrant**

Inclusion

Have given written informed consent prior to any trial-specific procedures / Are reliable, willing to be available for the duration of the trial and are willing to follow trial procedures / Are female and aged ≥ 18 years / Diagnosis of hormone receptor positive (HR+), HER2- breast cancer. Although not required as a protocol procedure, metastatic disease should be considered for biopsy whenever possible to reassess HR and HER2 status if clinically indicated. / To fulfill the requirement for HR+ disease, a breast cancer must express, by immunohistochemistry (IHC), at least one of the hormone receptors (estrogen receptor [ER], progesterone receptor [PgR]) as defined in the relevant American Society of Clinical Oncology (ASCO)/College of American Pathologists (CAP) Guidelines (Hammond et al. 2010). / To fulfill the requirement of HER2- disease, a breast cancer must not demonstrate, at initial diagnosis or upon subsequent biopsy, overexpression of HER2 by either IHC or in-situ hybridization (ISH) as defined in the relevant ASCO/CAP guidelines (Wolff et al. 2013). / Have locally advanced recurrent disease not amenable to resection or radiation therapy with curative intent or metastatic disease / Indication for endocrine based therapy in the metastatic setting / Have a performance status (PS) of ≤2 on the Eastern Cooperative Oncology Group (ECOG) scale / If central nervous system (CNS) metastases are known these have to be stable (radiotherapy finished for more than 14 days ago, no required steroid medication with more than 4 mg Dexamethasone per day) / Pre- and postmenopausal patients are allowed. Postmenopausal is defined as no menses for 12 months without an alternative medical cause. Women of Childbearing Potential (WOCBP, defined as not postmenopausal and not surgically or congenitally sterile) whose male partners are potentially fertile (e.g. no vasectomy) must use highly effective contraception methods for the duration of the trial and for at least 3 weeks after last dose of drugs used in the trial.Women of childbearing potential must use highly effective contraception methods for two years after the last dose of fulvestrant. Highly effective birth control methods that results in a failure rate of less than 1% per year include combined (estrogen and progestogen containing) hormonal contraception associated with inhibition of ovulation (oral, intravaginal, transdermal), progestogen-only hormonal contraception associated with inhibition of ovulation (oral, injectable, implantable), intrauterine device, intrauterine hormone-releasing system (IUS), bilateral tubal occlusion, vasectomized partner. Sexual abstinence is only considered a highly effective method if defined as refraining from heterosexual intercourse in the defined period. The reliability of sexual abstinence needs to be evaluated in relation to the duration of the trial and the preferred and usual lifestyle of the patient. / No prior therapy for metastatic disease (except for first line endocrine therapy for maximal 3 months prior to start of abemaciclib therapy and if no progress occurred before study entry) / Previous adjuvant endocrine therapy and (neo)adjuvant chemotherapy is allowed / Patients who received chemotherapy must have recovered (Common Terminology Criteria for Adverse Events [CTCAE] Grade ≤1) from the acute effects of chemotherapy except for residual alopecia or ≤ Grade 2 peripheral neuropathy prior to registration. A washout period of at least 21 days is required between last chemotherapy dose and registration (provided the patient did not receive radiotherapy). / Patients who received radiotherapy must have completed and fully recovered from the acute effects of radiotherapy. A washout period of at least 14 days is required between end of radiotherapy and registration. / **One of the following as defined by the RECIST v1. 1** (see Attachment 15.5): Measurable disease. At least one measurable lesion assessable using standard techniques by Response Evaluation Criteria In Solid Tumors Version 1.1 (RECIST v1.1). Tumor evaluation according to RECIST version 1.1 (based on local assessment) has to be performed within 28 days before trial registration. / Nonmeasurable bone-only disease (must be evaluable, but not necessarily measurable by RECIST). Nonmeasurable bone-only disease may include any of the following: blastic bone lesion, lytic bone lesions without a measurable soft tissue component, or mixed lytic-blastic bone lesions without a measurable soft tissue component. / The patient has adequate bone marrow and organ function evidenced by the following laboratory results: absolute neutrophil count (ANC) ≥ 1.5 × 109/L, Platelet count ≥ 100 × 109/L, Hemoglobin ≥ 8 g/dL, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) ≤ 2.0 × ULN (≤ 3 x ULN in case of liver metastases), Total Bilirubin ≤ 1.5 × ULN (with Gilbert's syndrome max. 2 x ULN), Serum Creatinine ≤ 2.0 mg/dl or 177µmol/L, Coagulation: International Normalized Ratio (INR) ≤ 1,5 / The patient is able to swallow oral medications / Willingness to use the provided CANKADO digital health application to report side effects and patient reported outcomes (The use of the CANKADO app is not mandatory for study participation, but is strongly recommended) / Negative pregnancy test before trial registration for women of child-bearing potential and highly effective contraception if the risk of conception exists and a negative serum pregnancy test within 7 days after the first dose of trial treatment. Pregnancy tests should be performed in premenopausal patients according to local standard

Exclusion Criteria:

see Link:

clinicaltrials.gov/NCT05362760

Study Test Center	PI / SC	Phone	E-Mail
Albertinen Krankenhaus (Hamburg)	**Ulrike Dörste** **Christiane Krümmel (SC)**	040-79006 896	christiane.kruemmel@immanuelalbertinen.de

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A Phase 3, Randomized, Open-label, Study to Compare the Efficacy and Safety of Adjuvant MK-2870 in Combination With Pembrolizumab (MK-3475) Versus Treatment of Physician's Choice (TPC) in Participants With Triple-Negative Breast Cancer (TNBC) Who Received Neoadjuvant Therapy and Did Not Achieve a Pathological Complete Response (pCR) at Surgery

Condition: Triple-Negative Breast Cancer
Primary Completion Date: 2030-12-16
Phase: III
Intervention/ Treatment: DRUG: **Capecitabine**_BIOLOGICAL: **Pembrolizumab/ Sacituzumab tirumotecan**

Inclusion
Has centrally confirmed TNBC, as defined by the most recent American Society of Clinical Oncology/College of American Pathologists (ASCO/CAP) guidelines / Has no evidence of locoregional or distant relapse, as assessed by the treating physician / Had neoadjuvant treatment based on the KEYNOTE-522 regimen (pembrolizumab with carboplatin/taxanes and pembrolizumab with anthracycline-based chemotherapy) followed by surgery according to National Comprehensive Cancer Network (NCCN) treatment guidelines for TNBC / Had adequate excision and surgical removal of all clinically evident disease in the breast and/or lymph nodes and have adequately recovered from surgery / Has non-pathologic complete response at surgery / Is able to continue on adjuvant pembrolizumab / Randomization must be conducted within 16 weeks from surgical resection / Completed adjuvant radiation therapy (if indicated) and recovered before randomization / Has provided tissue from the surgical resection for central laboratory determination of trophoblast cell surface antigen 2 (TROP2) status / If capable of producing sperm, the participant agrees to the following during the intervention period and for at least the time needed to eliminate each study intervention after the last dose of study intervention (120 days for sacituzumab tirumotecan and 95 days for capecitabine [no restriction for pembrolizumab]): agrees to refrain from donating sperm AND is either abstinent and agrees to remain abstinent or uses highly effective contraception / For females (assigned at birth), is not pregnant or breastfeeding and ≥1 of the following applies: is not a participant of childbearing potential (POCBP) OR is a POCBP and uses highly effective contraception after the last dose of study intervention (210 days for sacituzumab tirumotecan, 120 days for pembrolizumab, and 185 days for capecitabine). Abstains from breastfeeding during the study intervention period and for at least 120 days after study intervention / Participants who have AEs due to previous anticancer therapies must have recovered to ≤Grade 1 or baseline (except alopecia) / Human immunodeficiency virus (HIV)-infected participants must have well controlled HIV on antiretroviral therapy (ART) / An Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1 assessed within 7 days before first dose of study treatment / Participants who are hepatitis B surface antigen (HBsAg) positive are eligible if they have received hepatitis B birus (HBV) antiviral therapy for at least 4 weeks, and have undetectable HBV viral load prior to randomization
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT06393374

Study Test Center	PI / SC	Phone	E-Mail
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Dermatitis During Adjuvant Irradiation for BREAst Cancer: Grade ≥2 Radiation Dermatitis in Breast Cancer Patients with or Without a Mobile Application (Reminder-App)

Condition: Breast Cancer Female
Primary Completion Date: 2026-09-30
Phase: N/A
Intervention/ Treatment: OTHER: **Standard skin care**_ DEVICE: **Reminder App**

Inclusion
Histologically proven invasive breast cancer / Indication for adjuvant hypo-fractionated radiotherapy / Possession of and ability to use a smartphone / Female gender / Age ≥18 years / Written informed consent / Capacity of the patient to contract
Exclusion Criteria:
Pregnancy, Lactation / Expected non-compliance
see Link:

clinicaltrials.gov/NCT06483477

Study Test Center	PI / SC	Phone	E-Mail
UKSH Lübeck Radiotherapy	Prof. Dr. med. Dirk Rades		Dirk.Rades@uksh.de

EMBER-4: A Randomized, Open-Label, Phase 3 Study of Adjuvant Imlunestrant vs Standard Adjuvant Endocrine Therapy in Patients Who Have Previously Received 2 to 5 Years of Adjuvant Endocrine Therapy for ER+, HER2- Early Breast Cancer With an Increased Risk of Recurrence

Condition: Breast Neoplasms
Primary Completion Date: 2027-10
Phase: III
Intervention/ Treatment: DRUG: **Imlunestrant/ Tamoxifen/ Anastrozole/ Letrozole/ Exemestane**

Inclusion
Have a diagnosis of ER+, HER2- early-stage, resected, invasive breast cancer without evidence of distant metastasis. / Participants must have received at least 24 months but not more than 60 months of any adjuvant ET, from time of adjuvant ET initiation. / Participants may have received (neo) adjuvant chemotherapy and/or targeted therapy with a CDK4/6- or PARP- inhibitor. / Must have an increased risk of disease recurrence based on clinical-pathological risk features. / Have a Performance Status of 0 or 1 on the Eastern Cooperative Oncology Group scale. / Have adequate organ function.

Exclusion Criteria:
Have any evidence of metastatic disease (including contralateral ALN) or inflammatory breast cancer at primary breast cancer diagnosis. / Participants with more than a 6-month consecutive gap in therapy during the course of prior adjuvant ET. / Participants who have completed or discontinued prior adjuvant ET >6 months prior to screening. / Participants with a history of previous breast cancer are excluded, with the exception of ipsilateral DCIS treated by locoregional therapy alone ≥5 years ago. / Pregnant, breastfeeding, or expecting to conceive or father children within the projected duration of the trial, starting with the screening visit through 180 days after the last dose of study intervention. / Participant has previously received ET of any duration for breast cancer prevention (tamoxifen or AIs) or raloxifene. / Participants with a history of any other cancer. / Have serious preexisting medical conditions that, in the judgment of the investigator, would preclude participation in this study.

see Link:

clinicaltrials.gov/NCT05514054

Study Test Center	PI / SC	Phone	E-Mail
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A Phase Ib/III, Open-label, Randomised Study of Capivasertib Plus CDK4/6 Inhibitors and Fulvestrant Versus CDK4/6 Inhibitors and Fulvestrant in Hormone Receptor-Positive and Human Epidermal Growth Factor Receptor 2-Negative Locally Advanced, Unresectable or Metastatic Breast Cancer (CAPItello-292)

Condition: Locally Advanced (Inoperable) or Metastatic Breast Cancer
Primary Completion Date: 2027-11-01
Phase: III
Intervention/ Treatment: DRUG: **Capivasertib/ Fulvestrant/ Palbociclib/ Ribociclib/ Abemaciclib**

Key inclusion criteria for both phases:
Adult females (pre-/peri-/ and post-menopausal), and adult males. / Histologically confirmed HR+/ HER2- breast cancer determined from the most recent tumour sample (primary or metastatic) per the American Society of Clinical Oncology and College of American Pathologists guideline. To fulfil the requirement of HR+ disease, a breast cancer must express ER with or without co-expression of progesterone receptor. / Eligible for fulvestrant therapy and at least one of the following: palbociclib, ribociclib, or abemaciclib, as per local investigator assessment. Previous tolerance to specific CDK4/6 inhibitors and dose levels required. / Adequate organ and bone marrow functions. / Consent to provide a mandatory FFPE tumour sample.
Key inclusion criteria only for phase III:
Previous treatment with an ET (tamoxifen, AI, or oral SERD) as a single agent or in combination, with radiological evidence of breast cancer recurrence or progression while on, or within 12 months of, completing a (neo)adjuvant ET regimen. / Provision of mandatory blood samples at screening for central testing using an investigational ctDNA test to be stratified based on PIK3CA/AKT1/PTEN status. / Be eligible for fulvestrant and at least one out of palbociclib or ribociclib (depending on the available CDK4/6i options at time of enrolment), as per local investigator assessment. / Have measurable lesion(s) according to Response Evaluation Criteria in Solid Tumours version 1.1 (RECIST v1.1) or, in the absence of measurable disease, lytic or mixed bone lesions that can be assessed by computed tomography (CT) or magnetic resonance imaging (MRI).
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT04862663

Study Test Center	PI / SC	Phone	E-Mail
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12 „CAPTOR-BC“

This is a single-arm, open-label phase IV study of patients with advanced HR+/HER2- breast cancer who are treated first line with ribociclib and SoC endocrine treatment according to SmPC

Condition: Breast cancer Female
Primary Completion Date: 2026-10
Phase: IV
Intervention/ Treatment: DRUG: **Ribociclib**

Inclusion Criteria:
Indication for treatment with ribociclib in combination with endocrine therapy in the locally advanced or 1st line metastatic therapy setting according to SmPC. (Previous treatment with cycline dependent kinase 4/6 (CDK4/6) inhibitors is allowed in the adjuvant setting) / Written informed consent prior to beginning of trial specific procedures / Subject must be female and aged ≥ 18 years on the day of signing informed consent / Locally advanced or metastatic breast cancer not amenable to curative treatment / Patient has HER2-negative breast cancer confirmed by local laboratory defined as a negative in situ hybridization test or an immunohistochemistry (IHC) status of 0 or 1+. If IHC is 2+, a negative in situ hybridization (FISH, CISH, or SISH) test is required to confirm the HER2-negative status (based on the most recently analyzed tissue sample tested by a local laboratory / Histologically confirmed estrogen receptor (ER) positive and/ or progesterone receptor (PgR) positive breast cancer determined by core biopsy according to local in-house standard. / corrected QT (QTcF) interval < 450 ms / Adequate organ function amenable for treatment with ribociclib as assessed by local laboratory /
Women of childbearing potential must have a negative urine or serum pregnancy test within 72 h prior to study entry and be willing to use highly effective method of contraception for course of the trial through 21 days after the last dose of trial treatment. /
Patient must be willing and able to comply with scheduled visits, treatment plans, laboratory tests, and other trial procedures.

Exclusion Criteria:
Concurrent participation in a study with an investigational agent/device or within 14 days of study entry or 5 half-lives of the respective investigational agent/device, whichever is longer /
Patients who are not treated for advanced HR+, HER2- breast cancer in the first line therapy setting. / Patient not eligible for treatment with ribociclib according to SmPC or investigator's discretion /
Patients who are pregnant or lactating. / Patients with existing or patients who are at significant risk of developing corrected QT interval (QTc) prolongation. This includes / patients with long QT syndrome / uncontrolled or significant cardiac disease, including recent myocardial infarction, congestive heart failure, unstable angina and bradyarrhythmia / electrolyte abnormalities / Patients with known hypersensitivity to the active substance of ribociclib, soya, peanut or any other of the excipients of ribociclib. / Patients with active systemic infections (for example, bacterial infection requiring intravenous antibiotics at time of initiating study treatment, fungal infection, or detectable viral infection requiring systemic therapy) or viral load (such as known human immunodeficiency virus positivity or with known active hepatitis B or C, for example, hepatitis B surface antigen positive). / Patients with serious preexisting medical condition(s) that, in the judgment of the investigator, would preclude participation in this study (such as severe renal impairment, interstitial lung disease, severe dyspnea at rest or requiring oxygen therapy, history of major surgical resection involving the stomach or small bowel, or preexisting Crohn's disease or ulcerative colitis or a preexisting chronic condition resulting in clinically significant diarrhea). / Patient who do not agree to collection of biospecimens samples (blood, stool, tissue)

see Link: clinicaltrials.gov/NCT05452213

Study Test Center	PI / SC	Phone	E-Mail
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Jerusalem Krankenhaus Breast Center	Prof. Dr. med. Christian Schem Silke Kassner /SN)	040-44190-69/670	schem@mammazentrum.eu kassner@mammazentrum.eu
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NeoAdjuvant Dynamic Marker - Adjusted Personalized Therapy Comparing Trastuzumab-deruxtecan Versus Pacli-/Docetaxel+Carboplatin+Trastuzumab+Pertuzumab in HER2+ Early Breast cancer

Condition: HER2-Positive Early Breast cancer
Primary Completion Date: 2027-09-20
Phase: II
Intervention/ Treatment: Drug: **Trastuzumab deruxtecan/ SoC**

Inclusion Criteria:
Female patients with invasive, untreated HER2+ breast cancer (as assessed by local pathology) maximum 6 weeks before registration (standard-of-care diagnostic biopsy according to current AGO guidelines) / Age ≥18 years / ***Cohort 1****:* low- to intermediate-risk for recurrence as per investigator´s decision (recommendation: cT1c - cT2 (1 - ≤3cm), cN0; cT1a/b excluded), **Cohort 2:** intermediate- to high-risk for recurrence as per investigator´s decision (recommendation: cT2 (>3 - ≤5cm), cN0) / 3c. Elderly patients (≥ 65 years) may be assigned to any cohort as per investigator's decision / Written informed consent / LVEF ≥ 50% within 28 days before randomisation / Eastern Cooperative Oncology Group performance status (ECOG PS) 0-1 / Adequate organ and bone marrow function within 14 days before randomisation / Adequate treatment washout period before randomisation (refer to protocol for detailed information) / Evidence of post-menopausal status or negative serum pregnancy test for females of childbearing potential (refer to protocol for detailed information) 10. Female subjects must not donate, or retrieve for their own use, ova from the time of randomisation and throughout the study treatment period, and for at least 7 months after the final study drug administration. (refer to protocol for detailed information)
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT05704829

Study Test Center	PI / SC	Phone	E-Mail
Jerusalem Krankenhaus Breast Center	Prof. Dr. med. Christian Schem, Silke Kassner /SN)	040-44190- 69/670	studien@mammazentrum.eu kassner@mammazentrum.eu

NeoAdjuvant Dynamic Marker - Adjusted Personalized Therapy Comparing Trastuzumab-deruxtecan Versus Pacli-/Docetaxel+Carboplatin+Trastuzumab+Pertuzumab in HER2+ Early Breast cancer

Condition: HER2-Positive Breast cancer
Primary Completion Date: 2029-05
Phase: II
Intervention/ Treatment: Drug: **Trastuzumab deruxtecan/ Phesgo 1,200 MG / 600 MG / 30,000 UNT Per 15 ML Injection/ Phesgo 600 MG / 600 MG / 20,000 UNT in 10 mL Injection**

Inclusion Criteria:
To be eligible to participate in this trial, an individual must meet ALL the following criteria: / Patient must be capable to understand the purpose of the study and have signed written informed consent form (ICF) prior to beginning specific protocol procedures. / Male or female patients ≥ 18 years of age at the time of signing ICF. / Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1. / Life expectancy of ≥ 12 weeks at screening. / Evidence of HER2-overexpressing tumor status confirmed by any MEDSIR's designated central lab or patient has a pathology report confirming HER2-overexpression by local testing, preferably on the most recent available metastatic sample. In the latest case, tumor tissue or blood must be sent to any MEDSIR's designated central lab for confirmation of HER2 status. Analysis of the primary tumor sample will be accepted if the metastatic tissue is inaccessible. / Must have known estrogen receptor (ER) and progesterone receptor (PgR) status locally determined prior to study entry. / Unresectable locally recurrent or MBC documented by computerized tomography (CT) scan or magnetic resonance imaging (MRI) that is not amenable to resection with curative intent. / Evaluable disease as per Response Evaluation Criteria In Solid Tumors version 1.1 (RECIST v.1.1) criteria. / Willingness and ability to provide the most recently available formalin-fixed paraffin-embedded (FFPE) tumor tissue blocks at the time of the inclusion (mandatory). If archival tissue is not available, a newly obtained baseline biopsy of an accessible tumor lesion is required prior to start of study treatment. / No prior chemotherapy and/or HER2-targeted therapy for advanced disease (one prior line of endocrine therapy is allowed for MBC). / May have received adjuvant or neoadjuvant chemotherapy and/or HER2-targeted therapy before study treatment initiation, with a disease-free interval (DFI) from completion of the systemic treatment (excluding hormonal therapy) to metastatic diagnosis of at least 12 months. / Adequate hematologic and organ function, defined by the following: / Hematological (without platelet, red blood cell transfusion, and/or granulocyte colony-stimulating factor support within seven days before first study treatment dose): White blood cell (WBC) count > 3.0 x 109/L, absolute neutrophil count (ANC) ≥ 1.5 x 109/L, platelet count ≥ 100.0 x 109/L, and hemoglobin (Hb) ≥ 9.0 g/dL. / Hepatic: Serum albumin ≥ 2.5 g/dL; total bilirubin ≤ 1.5 times the upper limit of normal (x ULN) (≤ 3 x ULN in patients with known history of Gilbert's disease); alkaline phosphatase (ALP) ≤ 2.5 x ULN (≤ 5 × ULN in patients with liver and/or bone metastases); aspartate transaminase (AST) and alanine transaminase (ALT) ≤ 1.5 x ULN (≤ 3 x ULN in patients with liver metastases). / Renal: Creatinine clearance ≥ 50 mL/min as determined by Cockcroft Gault (using actual body weight). / Coagulation: International normalized ratio or prothrombin time and either partial thromboplastin or activated partial thromboplastin time ≤ 1.5 × ULN. / Resolution of all acute toxic effects of prior anticancer therapy to grade ≤ 1 as determined by the NCI-CTCAE v.5.0 criteria (except for alopecia or other toxicities not considered a safety risk for the patient at Investigator's discretion). / For women of childbearing potential who are sexually active with a non-sterilized male partner: must have a negative serum pregnancy test within 14 days before study treatment initiation. In addition, agreement to remain abstinent (refrain from heterosexual intercourse) or use one highly effective method of birth control or two effective contraceptive methods, as defined in the protocol from the time of screening until 7 months after the last dose of study treatments. Female patients must agree to refrain from egg cell donation and breastfeeding during this same period. / Male participants who intend to be sexually active with a female partner of childbearing potential must be surgically sterile or use highly effective contraceptive methods, or two effective contraceptive methods, as defined in the protocol from the time of screening until 4 months after the last dose of T-DXd or 7 months after the last dose of PHESGO to prevent pregnancy in a partner. Male participants must not donate or bank sperm during this same period. Not engaging in heterosexual activity (sexual abstinence) for the duration of the study and drug washout period is an acceptable practice if this is the preferred usual lifestyle of the participant the last dose of study treatments.
1.Patient must be accessible for treatment and follow-up.

Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT06172127

Study Test Center	PI / SC	Phone	E-Mail
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A Phase III, Multicenter, Randomized, Open-Label Study Evaluating the Efficacy and Safety of Inavolisib Plus Fulvestrant Versus Alpelisib Plus Fulvestrant in Patients With Hormone Receptor-Positive, HER2-Negative, PIK3CA Mutated, Locally Advanced or Metastatic Breast cancer Who Progressed During or After CDK4/6 Inhibitor and Endocrine Combination Therapy

Condition: HER2-positive Breast cancer
Primary Completion Date: 2026-10
Phase: III
Intervention/ Treatment: DRUG: **Inavolisib/ PHESGO/ Endocrine Therapy**

Inclusion Criteria:
Written informed consent for all study procedures according to local regulatory requirements prior to beginning specific protocol procedures. / Untreated, unilateral primary carcinoma of the breast, confirmed histologically by core biopsy. Fine-needle aspiration alone is not sufficient. Incisional biopsy is not allowed. / Tumor lesion in the breast with a palpable size of ≥ 2 cm or a sonographical size of ≥ 1 cm in maximum diameter. The lesion has to be measurable in two dimensions, preferably by sonography. / Patients must be in the following stages of disease: • cT1c - cT3 In patients with multifocal or multicentric breast cancer the largest lesion (target lesion) should be measured. -- HR+/HER2+ disease with centrally confirmed ER-status, PR-status, HER2-status, PIK3CA mutation (tumor), Ki-67 value and TILs on core biopsy (target lesion). ER/PgR positive and HER2-positive is defined according to current ASCO/CAP guidelines. PIK3CA mutational status will be determined by NGS. Formalin-fixed, paraffin-embedded (FFPE) breast tissue from core biopsy has therefore to be sent to the GBG central pathology laboratory prior to randomization./ Age >=18 years, female and male./ ECOG Performance status 0-1 / Normal cardiac function must be confirmed by ECG and cardiac ultrasound (LVEF or shortening fraction) within 3 months prior to randomization. Results for LVEF must be above 55%. / Laboratory requirements: **Hematology:** Absolute neutrophil count (ANC) >= 1.5/ nL --Platelets >= 100/ nL and Hemoglobin >= 10 g/dL (>= 6.2 mmol/L) Hepatic function --Total bilirubin < ULN except for patients with Gilbert's syndrome who may only be included if the total bilirubin is ≤ 3.0 × ULN or direct bilirubin ≤ 1.5 × ULN --AST and ALT ≤ 1.5x ULN and --Alkaline phosphatase ≤ 2.5x ULN / **Glucose Metabolism:** Fasting plasma glucose (FPG) < 126 mg/dL (7.0 mmol/L) --Glycosylated hemoglobin (HbA1c) < 5.7% / Negative pregnancy test (urine or serum) within 14 days prior to randomization for all women of childbearing potential. A woman is considered to be of childbearing potential if she is not hysterectomised or not postmenopausal. / Postmenopausal is defined as: --Age >= 60 years. --Age <60 years and >= 12 continuous months of amenorrhea with no identified cause other than menopause. --Surgical sterilization (bilateral oophorectomy). / For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of < 1% per year during the treatment period and for least 7 months after the last dose of PH-FDC SC. Examples of non hormonal contraceptive methods with a failure rate of < 1% per year include: bilateral tubal ligation; male partner sterilization; intrauterine devices. For men: men must remain abstinent or use a condom with a spermicidal product during the treatment period and for 7 months after the last dose of PH-FDC therapy to avoid exposing the embryo. Men and women must refrain from donating sperm/eggs during this same period. / **Complete staging work-up within prior to randomization with:** Bilateral mammography and/or breast MRI in combination with a breast ultrasound --Staging according to country guidelines --Other tests may be performed as clinically indicated. / Patient must be willing and able to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures.
see Link:

clinicaltrials.gov/NCT05306041

Study Test Center	PI / SC	Phone	E-Mail
Jerusalem Krankenhaus Breast Center	Prof. Dr. med. Christian Schem Silke Kassner (SC)	040-44190-69 557 040-44190-69 669	schem@mammazentrum.eu kassner@mammazentrum.eu

Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Discontinuation of CDK4/6 inhibitors in patients with metastatic HR positive, HER2 negative breast cancer with durable disease control: A randomized phase II trial of the AIO working groups breast cancer and quality of life

Condition: Breast cancer
Primary Completion Date: 2026
Phase: II
Intervention/ Treatment:

Inclusion Criteria:
Female patient has given written informed consent 2. Patient is ≥ 18 years of age at time of signing the written informed consent 3. Patient has been diagnosed with histologically confirmed metastatic adenocarcinoma of the breast 4. Patient has documented histological or cytological confirmation of estrogen receptor positive (ER+) and HER2 negative (HER2-) disease 5. Patient has no curative treatment option by surgery or radiotherapy 6. Patient was treated with CDK4/6 inhibitor plus endocrine therapy for at least 12 months with disease control (complete remission, partial remission or stable disease) as judged by the treating physician before planned study treatment initiation 7. Patient has a preserved performance status (ECOG ≤ 2) 8. Patient has adequate bone marrow, renal and hepatic function: a. Hemoglobin > 9.0 g/dL b. Absolute neutrophil count ≥ 1.5 x 109 /L c. Platelets ≥ 100 x 109 /L d. Calculated creatinine clearance ≥ 50 mL/min as determined by the Cockcroft-Gault equation e. AST (SGOT) / ALT (SGPT) and alkaline phosphatase ≤ 2.5x ULN f. Serum albumin > 30 g/L 9. Patients considered postmenopausal according to one of the following definition: a. Women 1 year ago or had chemotherapy-induced menopause with last menses >1 year ago 10. WOCBP must have a negative serum pregnancy test within 7 days prior to start of tria

Exclusion Criteria:
. Patient has active (or history of) brain or leptomeningeal metastases 2. Patient is pre- or perimenopausal. Patient is pregnant or breast feeding or planning to become pregnant within five times the half-life of the IMPs after the end of treatment. 3. Patient has significant cardiovascular disease, such as cardiac disease (New York Heart Association Class II or greater), myocardial infarction or cerebrovascular accident within 6 months prior to initiation of study treatment, unstable arrhythmias, or unstable angina 4. Patient has other concomitant or previous malignancy, except adequately treated in-situ carcinoma of the uterine cervix, basal or squamous cell carcinoma of the skin, cancer in complete remission for > 5 years 5. Patient has contraindication or shows hypersensitivity to the existing treatment with CDK4/6 inhibitor plus endocrine therapy 6. Patient shows evidence of any other disease, neurologic or metabolic dysfunction, physical examination finding or laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of any of the study medications, puts the patient at higher risk for treatmentrelated complications or may affect the interpretation of study results 7. Patient participated in another clinical study with an investigational medicinal product during the last 28 days before treatment initiation or 7 half-lives of previously used trial medication, whichever is longer or participate in such a study at the same time as this trial. 8. Any co-existing medical condition that in the investigator’s judgement will substantially increase the risk associated with the patient’s participation in the study. 9. Patient who has been incarcerated or involuntarily institutionalized by court order or by the authorities. 10. Patients who are unable to consent because they do not understand the nature, significance and implications of the clinical trial and therefore cannot form a rational intention in the light of the facts
see Link:

euclinicaltrials.eu: 2023-504141-31-00

Study Test Center	PI / SC	Phone	E-Mail
Hämatologisch-Onkologische Praxis Altona	PD Dr, med. Gunter Schuch Natascha Lueth (SC)	040-380212 4207 040-380212-4341	Gunter.Schuch@hopa.de Natascha.lueth@hopa-hamburg.de

Universitäres Cancer Center HAMBURG
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A Phase III, Open-Label, Randomised Study to Assess the Efficacy and Safety of Extended Therapy With Camizestrant Versus Standard Endocrine Therapy (Aromatase Inhibitor or Tamoxifen) in Patients With ER+/HER2- Early Breast cancer

Condition: Breast cancer, Early Breast Cancer
Primary Completion Date: 2027-04-19
Phase: III
Intervention/ Treatment: DRUG: **Camizestrant/ Tamoxifen/ Anastrozole/ Letrozole/ Exemestane**

Inclusion Criteria:
Women and Men, ≥18 years at the time of screening (or per national guidelines) / Histologically confirmed ER+/HER2- early-stage resected invasive breast cancer with high or intermediate risk of recurrence, based on clinical-pathological risk features, as defined in the protocol. / Completed adequate (definitive) locoregional therapy (surgery with or without radiotherapy) for the primary breast tumour(s), with or without (neo)adjuvant chemotherapy / Completed at least 2 years but no more than 5 years (+3 months) of adjuvant ET (+/- CDK4/6 inhibitor) / Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 1 / Adequate organ and marrow function

Exclusion Criteria:
Inoperable locally advanced or metastatic breast cancer / Pathological complete response following treatment with neoadjuvant therapy / History of any other cancer (except non-melanoma skin cancer or carcinoma in situ of the cervix or considered at very low risk of recurrence per investigator judgement) unless in complete remission with no therapy for a minimum of 5 years from the date of randomisation Any evidence of severe or uncontrolled systemic diseases which, in the investigator's opinion precludes participation in the study or compliance / Known LVEF <50% with heart failure NYHA Grade ≥2. Mean resting QTcF interval >480 ms at screening / Concurrent exogenous reproductive hormone therapy or non-topical hormonal therapy for non-cancer-related conditions / Any concurrent anti-cancer treatment not specified in the protocol with the exception of bisphosphonates (e.g. zoledronic acid) or RANKL inhibitors (eg, denosumab) / Previous treatment with camizestrant, investigational SERDs/investigational ER targeting agents, or fulvestrant / Currently pregnant (confirmed with positive serum pregnancy test) or breastfeeding /
Patients with known hypersensitivity to active or inactive excipients of camizestrant or drugs with a similar chemical structure or class to camizestrant. In pre-/peri-menopausal female and male patients, known hypersensitivity or intolerance to LHRH agonists, that would preclude the patient from receiving any LHRH agonist
see Link:

clinicaltrials.gov/NCT05774951

Study Test Center	PI / SC	Phone	E-Mail
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Schwerpunkt Onkologie & Hämatologie	Dr. med. Jan Wierecky Dorothea Zaech (SC)	040 35 71 777 526	**zaech@onkologie-hamburg.de**

Universitäres Cancer Center HAMBURG
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A Phase III, Open-Label, Randomised Study to Assess the Efficacy and Safety of Extended Therapy With Camizestrant Versus Standard Endocrine Therapy (Aromatase Inhibitor or Tamoxifen) in Patients With ER+/HER2- Early Breast cancer

Condition: Breast cancer
Primary Completion Date: 2026-12
Phase: III
Intervention/ Treatment: BIOLOGICAL: **Placebo/ GLSI-100**

Inclusion Criteria:

HLA-A*02-positive, unless being enrolled in the third non-HLA-A*02 arm / Histologically confirmed diagnosis of HER2/neu positive primary breast cancer for all tumors biopsied (multifocal, multicentric, or synchronous contralateral disease) / Completion of both neoadjuvant and adjuvant trastuzumab-based SoC breast cancer therapy / Stage I, II, or III at presentation with pathologic evidence of residual invasive carcinoma in the breast or axillary lymph nodes (residual disease) at surgery following completion of neoadjuvant therapy -OR- Stage III at presentation with pathologic complete response (pCR) at surgery following completion of neoadjuvant therapy / The subject can begin study therapy within one year of completion of adjuvant trastuzumab-based therapy and any other standard therapies, but, study therapy can be administered concurrently with endocrine therapy. / No clinical evidence of residual or persistent breast cancer per treating physician assessment / ECOG 0-2
Adequate organ function / Negative pregnancy test or evidence of post-menopausal status / If of childbearing potential, willing to use a form of highly effective contraception /
Subject must both reside in and have been treated for their cancer in the country in which the clinical site is located.

Exclusion Criteria:

Stage IV cancer or metastatic breast cancer at any time / Inflammatory breast cancer / Receiving other investigational agents / Receiving chemotherapy / Requiring long-term systemic treatment with corticosteroids or other immunosuppressive therapy / History of immunodeficiency or active autoimmune disease / A history of serious allergic reactions, including anaphylaxis, to human granulocyte-macrophage colony-stimulating factors such as sargramostim, yeast-derived products, or any component of the investigational product / Other malignancies except adequately treated in situ carcinoma of the cervix or basal cell or squamous cell carcinoma of the skin / Active infection / Known HIV infection with a detectable viral load within 6 months of the anticipated start of treatment. Note: Subjects on effective antiretroviral therapy with an undetectable viral load within 6 months of the anticipated start of treatment are eligible for this trial.

see Link:

clinicaltrials.gov/NCT05232916

Study Test Center	PI / SC	Phone	E-Mail
Helios Mariahilf	**Dr. med. Christoph Großmann**	040-79006 896	sekretariat.mariahilf@helios-gesundheit.de
Jerusalem Krankenhaus Breast Center	Prof. Dr. med. Christian Schem Silke Kassner (SC)	040-44190-69 557 040-44190-69 669	schem@mammazentrum.eu kassner@mammazentrum.eu

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„CAMBRIA-2“

Entities

This is a Phase III open-label study to assess if camizestrant improves outcomes compared to standard adjuvant endocrine therapy for patients with ER+/HER2- early breast cancer with intermediate-high or high risk for disease recurrence who completed definitive locoregional therapy (with or without chemotherapy). The planned duration of treatment in either arm within the study will be 7 years.

Condition: Breast cancer, Early Breast cancer
Primary Completion Date: 2030-03-04
Phase: III
Intervention/ Treatment: DRUG: **Camizestrant/ Tamoxifen/ Anastrozole/ Letrozole/ Exemestane/ Abemaciclib**

Inclusion Criteria:
Women and Men; ≥18 years at the time of screening (or per national guidelines) / Histologically confirmed ER+/HER2- early-stage resected invasive breast cancer with absence of any evidence of metastatic disease as defined in the protocol. / Completed adequate (definitive) locoregional therapy (surgery with or without radiotherapy) for the primary breast tumour(s), with or without (neo)adjuvant chemotherapy. Patients must be randomised within 12 months of definitive breast surgery. / Patients may have received up to 12 weeks of endocrine therapy prior to randomisation. / Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 1 / Adequate organ and bone marrow function

Exclusion Criteria:
Inoperable locally advanced or metastatic breast cancer / Pathological complete response following treatment with neoadjuvant therapy / History of any other cancer (except non-melanoma skin cancer or carcinoma in situ of the cervix or considered a very low risk of recurrence per investigator judgement) unless in complete remission with no therapy for a minimum of 5 years from the date of randomisation / Any evidence of severe or uncontrolled systemic diseases which, in the investigator's opinion precludes participation in the study or compliance "
Known LVEF <50% with heart failure NYHA Grade ≥2. / Mean resting QTcF interval > 480 ms at screening / Concurrent exogenous reproductive hormone therapy or non topical hormonal therapy for non-cancer-related conditions / Any concurrent anti-cancer treatment not specified in the protocol with the exception of bisphosphonates (e.g. zoledronic acid) or RANKL inhibitors (eg, denosumab) /
Previous treatment with camizestrant, investigational SERDs/investigational ER targeting agents, or fulvestrant / Currently pregnant (confirmed with positive serum pregnancy test) or breastfeeding. /
Patients with known hypersensitivity to active or inactive excipients of camizestrant or drugs with a similar chemical structure or class to camizestrant. In pre-/peri-menopausal female and male patients, known hypersensitivity or intolerance to LHRH agonists that would preclude the patient from receiving any LHRH agonist.
see Link:

clinicaltrials.gov/NCT05952557

Study Test Center	PI / SC	Phone	E-Mail
Jerusalem Krankenhaus Breast Center	Prof. Dr. med. Linn Wölber Silke Kassner /SN)	040-44190- 69/670	studien@mammazentrum.eu kassner@mammazentrum.eu
Albertinen Krankenhaus	**Ulrike Dörste** **Christiane Krümmel (SC)**	040- 79006 896	christiane.kruemmel@immanuelalbertinen.de

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The goal of this clinical study is to evaluate the potential benefits of intensified surveillance versus standard surveillance in medium-risk and high-risk early breast cancer patients.

Condition: Breast Cancer
Primary Completion Date: 2035-12
Phase: N/A
Intervention/ Treatment: DIAGNOSTIC TEST: **Determination of tumormarkers (CA27.29, CEA, CA125)/ Determination of CTC levels/ Determination of ctDNA levels_**
OTHER: **Biobanking of blood samples**

Inclusion Criteria:
Written informed consent for all study procedures according to local regulatory requirements prior to beginning specific protocol procedures. / Unilateral or bilateral primary invasive carcinoma of the breast, confirmed histologically. / Patients with intermediate- to high-risk early breast cancer defined as either / an indication for (neo-)adjuvant chemotherapy (regardless whether performed or not), **and/or** Large tumor (> 50 mm), **and/or** Positive lymph nodes, **and/or** High grade (>= G3). Indication to (neo-)adjuvant chemotherapy is seen as stated in the German S3 guideline for breast cancer as well as stated in the guidelines from the AGO. / A complete resection of the primary tumor, with resection margins free of invasive carcinoma. / Completion of primary anti-tumor therapy (adjuvant chemotherapy, surgery or radiotherapy, whichever occurs last) at least 4 weeks but no more than 24 months previously. Enrollment of patients during any kind of adjuvant therapy except chemotherapy (e.g., but not limited to endocrine therapy, antibody therapy, CDK4/6-inhibitors, PARP inhibitors, PI3K inhibitors, antibody-drug conjugates and other novel agents) is allowed. / Availability of primary tumor tissue from core biopsy or surgical removed tissue (FFPE Slide (≥ 6 mm³, min. 10 slides, thickness: 5 µm-10 µm, area >150 mm² and 1 H&E stained slide, minimum 20% tumor content) or FFPE Block (≥ 6 mm³ thickness: 100 µm, area: >150 mm² and 1 H&E stained slide, minimum 20% tumor content) or Genomic DNA extracted from FFPE slides or block (≥ 600 ng, Minimum volume: 25 µL, concentration: 20 ng/µL, buffer: 10 mM Tris pH 8, 1 mM EDTA)) at timepoint of enrollment. / Patients with primary systemic therapy: tissue from core biopsy / Patients receiving surgery as primary therapy: surgically removed cancer tissue. / No current clinical evidence for distant metastases. / Females or males ≥ 18 years and ≤ 75 years of age. / Performance status ≤ 1, Eastern Cooperative Oncology Group (ECOG) scale. / Patient must be willing and able to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures.

Exclusion Criteria:
Patients with a history of any secondary primary malignancy are ineligible with the following exceptions: in situ carcinoma of the cervix **or** adequately treated basal cell carcinoma of the skin **or** ipsi- **or** contralateral non-invasive carcinoma of the breast (DCIS). / Patients in pregnancy or breastfeeding. If a patient gets pregnant during the participation in the interventional phase of the study (Year 1-5), an end of intervention visit will be scheduled and the patient will enter the follow-up phase of the study. Pregnancy during the follow-up phase of the study is to be reported but does not lead to an exclusion of the study. / History of significant neurological or psychiatric disorders including psychotic disorders, dementia or seizures that would prohibit the understanding and giving of informed consent. /
Renal insufficiency with GFR < 30 mL/min. / Previous or concomitant cytotoxic or other systemic antineoplastic treatment that is not used for treating the primary breast cancer.

see Link: clinicaltrials.gov/NCT05658172

Study Test Center	PI / SC	Phone	E-Mail
UKE Gynecology	Prof. Dr. med. Volkmar Müller Dr. med. Lisa Steinhilper	040-7410-52510 0152-22815667	v.mueller@uke.de l.steinhilper@uke.de
Agaplesion Diakonieklinikum Hamburg	Dr. med. Celaletttin Ugur Mirjam Ahrens	040 790 20 2595	mirjam.ahrens@agaplesion.de
UKSH Lübeck Gynecology	Prof. Dr. med. Maggie Banys-Paluchowski Manuela Nohr (SC)	0451 500-41700 0451 500-41930	Maggie.Banys-Paluchowski@uksh.de Mauela.nohr@uksh.de
UKSH Kiel Gynecology	Prof. Dr. med. Marion Tina van Mackelenbergh Simone Walden (SC)	0431 500 21686 0431 500 21681	sgo@uksh.de simone.walden@uksh.de

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Gynaecological tumors

continue...

Contact at UCC Hamburg
Prof. Dr. med. Volkmar Müller, Tel.: 040 7410-52510

Prospective, multicentre phase III-trial in malignant extracranial germ cell tumors including a randomization between Carboplatin- and Cisplatin-combination standard chemotherapy based on a risk-stratification derived from the preceding MAKEI 96 trial and published data

Condition: Cancer of Endometrium Stage I/ cancer of Endometrium Stage II
Primary Completion Date: /
Phase: III
Intervention/ Treatment: DRUG: **Cisplatin**

Inclusion Criteria:
Confirmed extracranial MGCT up to 17 11/12 years of age or patients with ovarian primaries up to 29 / 11/12 years of age on the date of written informed consent / Diagnosis of a chemotherapy-naïve extracranial MGCT / Written informed consent of patients and/or their parents according to national law prior to trial entry / Karnofsky-Index of >70% or ECOG-Status 0-II / Negative pregnancy test within 7 days prior to starting treatment for female patients of childbearing potential, in case of ß-HCG secreting MGCT pregnancy has to be excluded by appropriate methods

Exclusion Criteria:
Patients with one or more of the following criterion are excluded:: Pregnancy / Lactation / Incomplete data at trial entry preventing risk group allocation / HIV-positivity / Live vaccine immunization within two weeks before start of protocol treatment / Sexually active adolescents not willing to use highly effective contraceptive method (pearl index <1) until 12 months after end of chemotherapy / Current or recent (within 30 days prior to date of informed written consent) treatment with another investigational drug or participation in another interventional clinical trial, except trials with different end points than MAKEI V that can run in parallel to MAKEI V without influencing that trial, e.g., trials on antiemetics, antimycotics, antibiotics, strategies for psychosocial support, etc. / Any other medical, psychiatric or drug related condition, or social condition incompatible with protocol treatmentNote: Patients excluded from the trial based on the presence of exclusion criteria may be eligible for registration as follow-up patients. They shall receive adequate treatment and will not be evaluated for primary and secondary objectives.Exclusion criteria in special indication: / Second malignancies / Negative preoperative tumour markers AFP and ß-HCG and solely pure teratoma histology• Known hypersensitivity against Cisplatin, Carboplatin, Etoposide, Ifosfamide or other ingredients of the medicinal product / Hearing impairment Grade 3 and 4 (CTCAE Vers.4.03

see Link:

Drks.de:DRKS00019921

Study Test Center	PI / SC	Phone	E-Mail
UKE Gynecology	Prof. Dr. med. Barbara Schmalfeld Juliane Granzow	040-7410 52510 040-7410 52396	b.schmalfeldt@uke.de j.granzow@uke.de

A Phase 3 Randomized, Open-label Study of Rinatabart Sesutecan (Rina-S) Versus Treatment of Investigator's Choice (IC) in Patients With Platinum Resistant Ovarian Cancer

Condition: Platinum-resistant Ovarian Cancer
Primary Completion Date: 2027-02
Phase: III
Intervention/ Treatment: DRUG: **Rina-S/ Paclitaxel/ Topotecan/ Pegylated liposomal doxorubicin (PLD)/ Gemcitabine**

Inclusion Criteria:
Participants must have histologically or cytologically confirmed high grade serous or endometrioid epithelial ovarian cancer, primary peritoneal cancer, or fallopian tube cancer. / Participants may be enrolled regardless of FRα expression level. / Participants must have received 1 to 4 prior lines of therapy. Participants must have progressed radiographically on or after their most recent line of therapy. / Participants must have received prior treatment **with the following therapies:** Platinum chemotherapy / Prior bevacizumab (or biosimilar) treatment is required, if labeled and available as standard of care per institutional guidelines, unless the participant has a documented contraindication or unless the participant is not eligible for treatment with bevacizumab (or biosimilar) due to precautions/intolerance / Participants with known or suspected deleterious germline or somatic breast cancer gene (BRCA) mutations and who achieved a complete or partial response to platinum-based chemotherapy must have been treated with a poly ADP-ribose polymerase (PARP) inhibitor as maintenance treatment unless the participant is not eligible for treatment with PARP inhibitor / Mirvetuximab soravtansine, **if:** / Mirvetuximab soravtansine is available in the enrollment region, **and** The participant is eligible based on positive FRα expression per Food and Drug Administration (FDA)-approved (or local equivalent) test, **and** The participant does not have a documented medical exception, including chronic corneal disorders, history of corneal transplantation, or active ocular conditions requiring ongoing treatment/monitoring, such as uncontrolled glaucoma, wet age-related macular degeneration requiring intravitreal injections, active diabetic retinopathy with macular edema, macular degeneration, presence of papilledema, and /or monocular vision. / Participants must have platinum-resistant disease: Participants who have only had 1 line of platinum-based therapy must have received at least 4 cycles of platinum therapy, and must have either had a response (CR or PR) or had non-measurable disease at the start of adjuvant platinum-based therapy, and then progressed between > 91 days and ≤ 183 days after the date of the last dose of platinum. / Participants who have received 2 to 4 lines of platinum-based therapy must have progressed on or within 183 days after the date of the last dose of platinum.
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT06619236

Study Test Center	PI / SC	Phone	E-Mail
Jerusalem Krankenhaus Breast Center	Prof. Dr. med. Felix Hilpert Silke Kassner /SN)	040-44190- 556 040-44190- 669	hilpert@mammazentrum.eu kassner@mammazentrum.eu

Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Phase III, Randomized, Double-blind, Placebo-controlled, Multi-centre, Global Study of Volrustomig in Women With High Risk Locally Advanced Cervical Cancer Who Have Not Progressed Following Platinum-based, Concurrent Chemoradiation Therapy (eVOLVE-Cervical)

Condition: Locally Advanced Cervical Cancer
Primary Completion Date: 2026-11-17
Phase: III
Intervention/ Treatment: BIOLOGICAL: **Volrustomig**_OTHER: **Placebo**

Inclusion Criteria:
Female. / Aged at least 15 years at the time of screening. / Body weight > 35 kg. / Histologically documented FIGO 2018 Stage IIIA to IVA cervical adenocarcinoma, cervical squamous carcinoma, or cervical adenosquamous carcinoma, with no evidence of metastatic disease. / Initial staging procedures performed no more than 42 days prior to the first dose of CCRT. / Provision of FFPE tumor sample to assess the PD-L1 expression. / Must not have progressed following CCRT, participants with persistent disease after definitive CCRT must not be amenable to other available therapies with curative intent. / WHO/ECOG performance status of 0 or 1. / Adequate organ and bone marrow function. / Capable of providing signed informed consent.

Exclusion Criteria:
Diagnosis of small cell (neuroendocrine) or mucinous adenocarcinoma of cervical cancer. / Evidence of metastatic disease. / Intent to administer a fertility-sparing treatment regimen. / History of organ transplant or allogenic stem cell transplant. / Active or prior documented autoimmune or inflammatory disorders. / Uncontrolled intercurrent illness. / History of another primary malignancy except for a) Malignancy treated with curative intent with no known active disease ≥2 years before the first dose of study intervention; b) Adequately treated nonmelanoma skin cancer or lentigo maligna, or carcinoma in situ without evidence of disease. / Unresolved toxicities from previous CCRT except for irreversible toxicity that is not reasonably expected to be exacerbated. / Prior history or presence of vesicovaginal, colovaginal, or rectovaginal fistula. / History of anaphylaxis to any biologic therapy or vaccine. / Current or prior use of immunosuppressive medication within 14 days before the first dose of the study intervention is excluded. The following are exceptions to this criterion: a) Intranasal, inhaled, topical steroids, or local steroid injections (eg, intraarticular injection); b) Steroids as premedication for hypersensitivity reactions (eg, CT scan premedication or chemotherapy premedication) or a single dose for palliative purpose (eg, pain control). / Patients who have undergone a previous hysterectomy, including a supracervical hysterectomy, or will have a hysterectomy as part of their initial cervical cancer therapy. / Any prior (besides prior CCRT) or concurrent treatment for cervical cancer. / Major surgical procedures within 4 weeks prior to the first dose of the study intervention or still recovering from prior surgery. / Exposure to immune mediated therapy prior to the study for any indication. 1.Receipt of live attenuated vaccine within 30 days prior to the first dose of the study intervention. / Participants with a known allergy or hypersensitivity to the study intervention, or any excipients of the study intervention.
2.see Link:

clinicaltrials.gov/NCT06079671

Study Test Center	PI / SC	Phone	E-Mail
UKE Gynecology	Prof. Dr. med. Linn Wölber Dana Bendik-Stoik	040-7410 23800 040-7410 51430	lwoelber@uke.de d.bendig-stoik@uke.de

A randomized, open-label, phase 3 study of sacituzumab govitecan versus physician's choice treatment in patients with endometrial cancer who have received prior platinum-based chemotherapy and anti-PD-1/PD-L1 immunotherapy

Condition: Endometrial Cancer
Primary Completion Date: 2025-01-31
Phase: III
Intervention/ Treatment: DRUG: **DRUG: Selinexorle/ Matching Placebo for Selinexor**

Inclusion
At least 18 years of age at the time of signing informed consent. / Histologically confirmed EC including: endometrioid, serous, undifferentiated, and carcinosarcoma. / TP53 wt assessed by next generation sequencing (NGS), evaluated by a central vendor. / Completed a single line, at least 12 weeks of platinum-based therapy (not including adjuvant or neoadjuvant therapy for Stage I-III disease) and achieved confirmed partial or complete response (PR or CR) by imaging, according to RECIST version 1.1. The participants should have received treatment for: / Primary Stage IV disease, defined as:
had a primary or later debulking surgery during first-line platinum-based therapy with R0 resection (R0 resection indicates a macroscopic complete resection of all visible tumor) and achieved CR after at least 12 weeks platinum-based therapy, **OR** had a primary or later debulking surgery during first-line platinum-based therapy with R1 resection (R1 resection indicates incomplete removal of all macroscopic disease) and achieved PR or CR after at least 12 weeks platinum-based chemotherapy, **OR** had no surgery and achieved PR or CR after at least 12 weeks platinum-based chemotherapy **OR** At first relapse (i.e., relapse after primary therapy including surgery and/or chemotherapy and/or immunotherapy for Stage I-IV disease), defined as: / had Stage I - III disease at diagnosis and received, at initial diagnosis, adjuvant chemotherapy and relapsed later. Participants should have PR or CR after at least 12 weeks of platinum-based chemotherapy compared with the start of this chemotherapy at the time of relapse, / had Stage I-III disease at diagnosis and did not receive adjuvant chemotherapy at initial diagnosis and relapsed later. Participants should have PR or CR after at least 12 weeks of platinum-based chemotherapy compared with the start of this chemotherapy at the time of relapse, **OR** had Stage IV disease at diagnosis and received initially chemotherapy with or without surgery and relapsed later. At the time of relapse, participants should have PR or CR after at least 12 weeks of platinum-based chemotherapy compared with the start of this chemotherapy at the time of relapse. / Previous treatment with anti-programmed cell death protein 1(PD-1) or anti-programmed death-ligand 1(PD-L1) monoclonal antibody and concomitant biologic agents (e.g., bevacizumab, trastuzumab) is allowed. / Must be able to initiate study drug 3 to 8 weeks after completion of their final dose of chemotherapy. / Eastern Cooperative Oncology Group (ECOG) performance status of 0-1. / Participants must have adequate bone marrow function and organ function within 2 weeks before starting study drug as defined by the following laboratory criteria: / Hepatic function: total bilirubin up to less than (<) 3*upper limit of normal (ULN); alanine aminotransferase (ALT) and aspartate aminotransferase (AST) less than or equal to (<=) 2.5*ULN in participants without liver metastasis. For participants with known liver involvement of their tumor: AST and ALT (<=) 5*ULN / Hematopoietic function within 1 week: Absolute neutrophil count (ANC) greater than or equal to (>=) 1.5*10^9/liter (L); platelet count >= 100*10^9/L; hemoglobin >= 9.0 gram per deciliter (g/dL) per local laboratory results / Renal function: estimated creatinine clearance (CrCl) of >= 20 milliliter per minute (mL/min), calculated using the standard local formula, as applicable / - In the opinion of the Investigator, the participant must: / Have a life expectancy of at least 12 weeks, and / Be fit to receive investigational therapy / Premenopausal females of childbearing potential must have a negative pregnancy test (serum β-human chorionic gonadotropin test) prior to the first dose of study drug. Female participants of childbearing potential must agree to use highly effective methods of contraception throughout the study and for 90 days following the last dose of study drug. / Written informed consent signed in accordance with federal, local, and institutional guidelines prior to the first screening procedure.
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT05611931

Study Test Center	PI / SC	Phone	E-Mail
UKE Gynecology	Prof. Dr. med. Barbara Schmalfeld Juliane Granzow	040-7410 52510 040-7410 52396	b.schmalfeldt@uke.de j.granzow@uke.de

A randomized, open-label, phase 3 study of combination therapy with avutometinib plus defactinib versus investigator's choice in patients with recurrent low-grade serous ovarian cancer

Condition: Low Grade Serous Ovarian Cancer
Primary Completion Date: 2028-10-15
Phase: III
Intervention/ Treatment: DRUG: **DRUG: Avutometinib/ Defactinib/ Pegylated iposomal doxorubicin/ Paclitaxel/ Letrozole/ Anastrozole**

Inclusion
Histologically proven LGSOC (ovarian, fallopian, peritoneal) / Documented mutational status of KRAS by a validated tumor-tissue based diagnostic test. / Suitable for treatment with at least one of the Investigator's Choice of Treatments:pegylated liposomal doxorubicin, paclitaxel, letrozole, anastrozole. / Progression or recurrence of LGSOC after at least one prior systemic therapy for metastatic disease. Measurable disease according to RECIST v1.1. / An Eastern Cooperative Group (ECOG) performance status ≤ 1. / Adequate organ function. / Adequate recovery from toxicities related to prior treatments. / For patients with reproductive potential, a negative pregnancy test must be confirmed and agreement to use highly effective method of contraceptive. / Willingness to comply with the scheduled visits, treatment plan, laboratory tests and other study procedures.

Exclusion Criteria:
Systemic anti-cancer therapy within 4 weeks of the first dose of study therapy. / Co-existing high-grade serous ovarian cancer or mixed histology. / Prior treatment with avutometinib, defactinib, or other FAK inhibitors. / History of prior malignancy with recurrence <3 years from the time of enrollment. / Major surgery within 4 weeks, minor surgery within 1 week, or palliative radiotherapy within 1 week of the first dose of study intervention. / Symptomatic brain metastases requiring steroids or other interventions, known leptomeningeal metastases, or spinal cord compression. / An active skin disorder that has required systemic therapy within one year of the first dose of study intervention. / History of medically significant rhabdomyolysis. / For subjects with prior MEK or RAF exposure, Grade 4 toxicity is deemed related to the MEK inhibitor. / Symptomatic bowel obstruction within 3 months of the first dose of study intervention / Concurrent ocular disorders. / Concurrent heart disease or severe obstructive pulmonary disease. / Active or past medical history of interstitial lung disease/pneumonitis, including drug-induced or radiation pneumonitis, pulmonary fibrosis, or adult respiratory distress syndrome (ARDS). / Subjects with the inability to swallow oral medications. / History of hypersensitivity to any of the active agents or ingredients of study intervention: peanut, soya, polyoxyl castor oil, etcetc.). Prior hypersensitivity to anthracyclines or anthracenediones if the use of pegylated liposomal doxorubicin (PLD) is planned. / Pregnant or breastfeeding.
Active, uncontrolled infection (bacterial, viral, or fungal) requiring systemic therapy.
see Link:

clinicaltrials.gov/NCT06072781

Study Test Center	PI / SC	Phone	E-Mail
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A randomized clinical trial comparing laparoscopic or robotic radical/simple hysterectomy with abdominal radical/simple hysterectomy in patients with early-stage cervical cancer

Condition: CervicalCancer
Primary Completion Date: 2033-07
Phase: N/A
Intervention/ Treatment: PROCEDURE: **Laparoscopic or robot-assisted radical/simple hysterectomy/ Abdominal radical/simple hysterectomy**

Inclusion
Histologically confirmed primary adenocarcinoma, squamous cell carcinoma or adenosquamous carcinoma of the uterine cervix / Patients with FIGO stage IA2, IB1, or IB2 disease (<4 cm) / Patients undergoing radical hysterectomy according either to Type II or III (Piver Classification) or to Type B or C (Querleu and Morrow classification) / **OR** Simple hysterectomy can be considered for patients with low-risk early-stage cervical cancer (SHAPE criteria: tumor < 2cm, < 10 mm depth of stromal invasion (LEEP/cone). Simple hysterectomy has to be performed as extrafascial hysterectomy and the preparation of a max. 5mm vaginal cuff is required to ensure negative margins. / Performance status of ECOG 0-1 / Patient must be suitable candidates for surgery with preoperative MRI and available for assessment of serious adverse events up to one year post-surgery / Patients who have signed an approved Informed Consent / Patients with a prior malignancy only if > 5 years previous with no evidence of disease / Females, aged 18 years or older

Exclusion Criteria:
Any histology other than an adenocarcinoma, squamous cell carcinoma, or adenosquamous carcinoma of the uterine cervix / Tumor size of 4 cm and greater, estimated by either magnetic resonance imaging (MRI) or clinical examination / FIGO stage IB3 - IV / Patients with a history of pelvic or abdominal radiotherapy / Patients with evidence of metastatic disease by conventional imaging studies, enlarged pelvic or aortic lymph nodes > 2 cm, or histologically positive lymph nodes / Serious concomitant systemic disorders incompatible with the study (at the discretion of the investigator) / Patients unable to withstand prolonged lithotomy and steep Trendelenburg position / Patient compliance and geographic proximity that do not allow adequate follow-up / Women who are pregnant / Patients with contraindications to surgery / Patients with secondary invasive neoplasm in the last 5 years (except non-melanoma skin cancer, breast cancer T1 N0 M0 grade 1 or 2 without any signs of recurrence or activity)

see Link:

clinicaltrials.gov/NCT06489795

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

„AGO-Ovar 27“, WoO

Entities

This is a multi-center, prospective, open-label, phase II trial. Patients with suspected advanced ovarian cancer planned to undergo diagnostic laparoscopy for histologic confirmation and evaluation of disease spread will be registered into the trial after providing a 1st written informed consent.

Condition: Epithelial Ovarian cancer
Primary Completion Date: 2028-06
Phase: II
Intervention/ Treatment: DRUG: **Olaparib, Durvalumab**

Inclusion Criteria: screening phase
Patients with presumed and previously untreated advanced stage ovarian cancer planned to undergo laparoscopy for histologic diagnosis and treatment planning / Patients willing and able to comply with the study protocol for the duration of the study including undergoing treatment and scheduled visits and examinations including follow up / Patients able and willing to provide fresh frozen biopsy samples from laparoscopy as well as primary debulking for translational endpoints as well as serial liquid biopsies / Patients able and willing to provide formaldehyde-fixed paraffin embedded (FFPE) tissue samples from laparoscopy and primary debulking surgery / Patients aged ≥18 years / Patients must be capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol / Provision of signed and dated, written ICF for the mandatory biomarker and genetic re-search as well as the clinical/therapeutic part of the study prior to any mandatory study specific procedures, sampling, and analyses / Eastern cooperative oncology group (ECOG) performance status 0-1 (see Appendix 1) / Patients must have a life expectancy ≥16 weeks
Ability to take oral medication / Postmenopausal or evidence of non-childbearing status for women of childbearing potential (WOCBP): negative serum pregnancy test within 28 days of study treatment and confirmed neagtive urine or serum pregnancy test prior to treatment on day 1. / **Postmenopausal is defined as:** Amenorrheic for 1 year or more following cessation of exogenous hormonal treatments / Luteinizing hormone (LH) and Follicle stimulating hormone (FSH) levels in the post menopausal range for women under 50 / radiation-induced oophorectomy with last menses >1 year ago / chemotherapy-induced menopause with >1 year interval since last menses / surgical sterilisation (bilateral oophorectomy or hysterectomy) / Women of childbearing potential (WOCBP) and their partners, who are sexually active, must agree to the use of 2 highly effective forms of contraception in combination. This should be started from the signing of the informed consent and continue throughout the period of taking study treatment and for at least 6 months after last dose of study drug(s), or they must totally/truly abstain from any form of sexual intercourse. /**treatment phase:** Confirmed advanced (FIGO IIB/III/IV) high-grade, non-mucinous, non-clear cell epithelial ovarian, fallopian tube or primary peritoneal cancer or known (BReast cancer) BRCA mutation and any histologic type / Planned primary debulking surgery after confirmation of diagnosis and disease evaluation during laparoscopy / Body weight >30kg / Patients must have normal organ and bone marrow function measured within 28 days prior to administration of study treatment as defined below: Haemoglobin ≥10.0 g/dL with no blood transfusion in the past 28 days / Absolute neutrophil count (ANC) ≥1.5×10^9/L / Platelet count ≥100×10^9/L / Total bilirubin ≤1.5 × institutional upper limit of normal (ULN) / Aspartate aminotransferase (AST), serum glutamic oxaloacetic transaminase (SGOT) / alanine aminotransferase (ALT), serum glutamic pyruvate transaminase (SGPT) ≤2.5 × institutional upper limit of normal unless liver metastases are present in which case they must be ≤5×ULN. (cave: patients with intrahepatic metastases affecting liver function test might not be candidates for primary debulking surgery) / Patients must have creatinine clearance estimated of ≥51 mL/min using the Cockcroft-Gault equation or based on a 24 hour urine test: / Estimated creatinine clearance=((140-age [years])*weight (kg))/(serum creatinine (mg/dL)*72)(* 0,85) 17. / Patients must have successfully contributed blood and tissue samples as per requirements.
see Link:

clinicaltrials.gov/NCT04644289

Study Test Center	PI / SC	Phone	E-Mail
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Niraparib vs Niraparib in Combination With Bevacizumab in Patients With Carboplatinum-taxane Based Chemotherapy in Advanced Ovarian cancer (A Multicentre Randomised Phase III Trial)

Condition: Ovarian cancer, Fallopian Tube cancer, Peritoneal cancer
Primary Completion Date: 2030-09
Phase: III
Intervention/ Treatment: DRUG: **Carboplatin, Paclitaxel, Bevacicumab, Niraparib**

Inclusion Criteria:

Signed written informed consent obtained prior to initiation of any study-specific procedures and treatment as confirmation of the patient's awareness and willingness to comply with the study requirements. / Female patients ≥ 18 years with histologically confirmed primary advanced invasive high grade epithelial ovarian cancer, peritoneal cancer, or fallopian tube cancer FIGO III/IV (except FIGO stage IIIA2 without nodal involvement) according to recent FIGO classification (= FIGO stage IIIB - IV according to FIGO 2009 classification). / All patients must have had either upfront primary debulking surgery OR plan to undergo chemotherapy with interval debulking surgery. / Patients must have available tumor samples to be sent to central laboratory as formalin-fixed, paraffin-embedded (FFPE) sample for determination of BRCA status prior to randomization for stratification. / Patients must be able to commence systemic therapy within 8 weeks of cytoreductive surgery. / Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0-1. / Estimated life expectancy > 3 months. / Adequate bone marrow function (within 28 days prior to day 1, cycle 1) / Absolute Neutrophil Count (ANC) ≥ 1.5 x 10^9/L / Platelets (PLT) ≥ 100 x 10^9/L / Hemoglobin (Hb) ≥ 9 g/dL (can be post-transfusion) / Adequate coagulation parameters (within 28 days prior to day 1, cycle 1) / Patients not receiving anticoagulant medication who have an International Normalized Ratio (INR) ≤ 1.5 and an Activated ProThrombin Time (aPTT) ≤ 1.5 x institutional upper limit of normal (ULN). / The use of full-dose oral or parenteral anticoagulants is permitted as long as the INR or aPTT is within therapeutic limits (according to institution medical standard) and the patient has been on a stable dose of anticoagulants for at least two weeks at the time of day 1, cycle 1. / Adequate liver and kidney function (within 28 days prior to day 1, cycle 1) / Total bilirubin ≤ 1.5 x ULN (≤ 2.0 x ULN in patients with known Gilbert's syndrome) OR direct bilirubin ≤ 1.0 x ULN. / Aspartate aminotransferase / Serum Glutamic Oxaloacetic Transaminase (ASAT/SGOT) and Alanine aminotransferase / Serum Glutamic Pyruvate Transaminase (ALAT/SGPT) ≤ 2.5 x ULN, unless liver metastases are present, in case of liver metastases values must be ≤ 5 x ULN. / Urine dipstick for proteinuria < 2+. If urine dipstick is ≥ 2+, 24 hour urine must demonstrate ≤ 1 g of protein in 24 hours. / Serum creatinine ≤ 1.5 x upper limit of normal (ULN) or calculated creatinine clearance ≥ 30 mL/min using the Cockcroft-Gault equation. / Patients must have normal blood pressure (BP) or adequately treated and controlled BP, with a systolic BP of ≤ 140 mmHg and diastolic BP of ≤ 90 mmHg for eligibility. Patients must have a BP of ≤ 140/90 mmHg taken in the clinic setting by a medical professional within 4 weeks prior to day 1, cycle 1. / Negative urine or serum pregnancy test within 7 days prior to day 1, cycle 1 in women of childbearing potential (WOCBP), confirmed prior to treatment on day 1. / For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use a highly effective contraceptive method with a failure rate of < 1% per year during the treatment period and for at least 6 months after administration of the last dose of medication. / A woman is considered to be of childbearing potential if she is postmenarcheal, has not reached a postmenopausal state (≥ 12 continuous months of amenorrhea with no identified cause other than menopause), and has not undergone surgical sterilization (removal of ovaries, fallopian tubes, and/or uterus). / Examples of contraceptive methods with a failure rate of < 1% per year include but are not limited to bilateral tubal ligation and/or occlusion, male sterilization, and intrauterine devices. The reliability of sexual abstinence should be evaluated in relation to the duration of the clinical study and the preferred and usual lifestyle of the patient. Periodic abstinence (e.g., calendar, ovulation, symptothermal, or postovulation methods) and withdrawal are not acceptable methods of contraception. / Willingness and ability to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures, that include the completion of patient-reported outcomes questionnaires.

see Link:

clinicaltrials.gov/NCT05009082

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Prospective, multicentre phase III-trial in malignant extracranial germ cell tumors including a randomization between Carboplatin- and Cisplatin-combination standard chemotherapy based on a risk-stratification derived from the preceding MAKEI 96 trial and published data

Condition: cancer of Endometrium Stage I/ cancer of Endometrium Stage II
Primary Completion Date: /
Phase: III
Intervention/ Treatment: DRUG: **Cisplatin**

Inclusion Confirmed extracranial MGCT up to 17 11/12 years of age or patients with ovarian primaries up to 29 / 11/12 years of age on the date of written informed consent / Diagnosis of a chemotherapy-naïve extracranial MGCT / Written informed consent of patients and/or their parents according to national law prior to trial entry / Karnofsky-Index of >70% or ECOG-Status 0-II / Negative pregnancy test within 7 days prior to starting treatment for female patients of childbearing potential, in case of ß-HCG secreting MGCT pregnancy has to be excluded by appropriate methods

Exclusion Criteria:

Patients with one or more of the following criterion are excluded:: Pregnancy / Lactation / Incomplete data at trial entry preventing risk group allocation / HIV-positivity / Live vaccine immunization within two weeks before start of protocol treatment / Sexually active adolescents not willing to use highly effective contraceptive method (pearl index <1) until 12 months after end of chemotherapy / Current or recent (within 30 days prior to date of informed written consent) treatment with another investigational drug or participation in another interventional clinical trial, except trials with different end points than MAKEI V that can run in parallel to MAKEI V without influencing that trial, e.g., trials on antiemetics, antimycotics, antibiotics, strategies for psychosocial support, etc. / Any other medical, psychiatric or drug related condition, or social condition incompatible with protocol treatmentNote: Patients excluded from the trial based on the presence of exclusion criteria may be eligible for registration as follow-up patients. They shall receive adequate treatment and will not be evaluated for primary and secondary objectives.Exclusion criteria in special indication: / Second malignancies / Negative preoperative tumour markers AFP and ß-HCG and solely pure teratoma histology• Known hypersensitivity against Cisplatin, Carboplatin, Etoposide, Ifosfamide or other ingredients of the medicinal product / Hearing impairment Grade 3 and 4 (CTCAE Vers.4.03

see Link:

Drks.de:DRKS00019921

Study Test Center	PI / SC	Phone	E-Mail
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Universitätsklinikum Hamburg-Eppendorf

Pelvic and Para-aortic Lymphadenectomy in Patients With Stage I or II Endometrial cancer With High Risk of Recurrence

Condition: cancer of Endometrium Stage I or II
Primary Completion Date: 2028-02-15
Phase: N/A
Intervention/ Treatment: PROCEDURE: **Standard surgical procedure for endometrial cancer/ systematic lymphadenectomy (LNE)**

Inclusion Criteria:
histologically confirmed EC of clinical stages T1b and T2 (all histological types) and stage T1a G3 type 1 (endometrioid, endometriod with squamous differentiation, mucinous) or type 2 tumors (any percentage of serous or clear cell component) or carcinosarcoma / a) no previous surgery concerning EC (primary surgery) or b) surgery after hysterectomy (e.g. for presumed low risk endometrial cancer) is allowed within 8 weeks after hysterectomy if no LNE was performed (secondary surgery) / absence of bulky lymph nodes / performance status ECOG 0-1 / age 18 - 75 years / written informed consent adequate compliance

Exclusion Criteria:
stage pT1a, G1 or G2 tumors of type 1 histology / sarcomas (except for carcinosarcoma = malignant mixed Müllerian tumor) / EC of FIGO stages III or IV (except for microscopical lymph node metastases) evidence of extrauterine disease by visual inspection / recurrent EC / preceding chemo-, radio, or endocrine therapy for EC / any concomitant disease not allowing surgery including lymphadenectomy and/or chemotherapy / any medical history indicating excessive peri-operative risk / any current medication containing considerable surgical risk (e.g. bleeding: due to oral anticoagulating agents) / any known disorder or circumstances making participation in trial and follow-up questionable. Insufficient compliance is expected. / patients with second malignancies if disease or treatment might have an impact on the patient's prognosis / known HIV-infection or AIDS / simultaneous participation in other clinical trials if not permitted by the steering committee (translational or QoL studies not interfering with the objectives of ECLAT are allowed)

see Link:

clinicaltrials.gov/NCT03438474

Study Test Center	PI / SC	Phone	E-Mail
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Maintenance Therapy With Aromatase Inhibitor in Epithelial Ovarian Cancer: a Randomized Double-blinded Placebo-controlled Multi-centre Phase III Trial (ENGOT-ov54/Swiss-GO-2/MATAO), Including LOGOS (Low Grade Ovarian Cancer Sub-study).

Condition: Ovarian Neoplasm Epithelial/ Fallopian Tube Neoplasms/ Peritoneal Neoplasms/ High-grade Serous Ovarian Carcinoma (HGSOC)/ Low-grade Serous Ovarian Carcinoma (LGSOC)/ Ovarian Endometrioid Carcinom

Estimated Completion Date: 2025-10-01

Phase: III

Intervention/ Treatment: DRUG: **Letrozole 2.5mg**_OTHER: **Placebo**

Inclusion Criteria:

Patients must be ≥ 18 years of age / Willing and able to attend the visits and to understand all study-related procedures. / Primary, newly diagnosed FIGO Stage II to IV and histologically confirmed low or high grade serous or endometrioid epithelial ovarian/fallopian tube/peritoneal cancer / (Interval-) debulking performed ECOG-Performance Status 0-2 / Signed informed consents (ICF-1; ICF-2) / Paraffin-embedded tissue or paraffin-embedded cell block (from ascites) available / Positivity (≥ 1%) for ER expression (only determined by Histopathology Core Facility of MATAO trial) / At least 4 cycles of platinum-based chemotherapy (neoadjuvant allowed) / Negative serum pregnancy test in women of childbearing potential who will get/have gotten a surgical resection or radiation sterilization, prior to the intervention in the therapeutical maintenance setting.

Exclusion Criteria:

Progressive disease at the end of adjuvant treatment as defined in chapter 9.2.1 of protocol / Women of childbearing potential (not having undergone a surgical or radiation sterilization and not getting a surgical resection, prior to the intervention in the therapeutical maintenance setting) / Pregnant or lactating women / Any other malignancy within the last 5 years which has impact on the prognosis of the patient / < 4 cycles of chemotherapy in total / Contraindications to endocrine therapy / Inability or unwillingness to swallow tablets / Patients with a known intolerance to galactose, lactase deficiency and glucose-galactose malabsorption

see Link:

clinicaltrials.gov/NCT04111978

Study Test Center	PI / SC	Phone	E-Mail
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Universitätsklinikum Hamburg-Eppendorf

Pembrolizumab in Combination With Lenvatinib in Pts With Recurrent, Persistent, Metastatic or Locally Advanced Vulvar Cancer Not Amenable to Curative Surgery or Radiotherapy

Condition: Recurrent Vulvar Cancer/ Persistent Vulvar Cancer/ Metastatic Vulva Cancer/ Locally Advanced Vulvar Cancer
Primary Completion Date: 2027-10-30
Phase: II
Intervention/ Treatment: DRUG: **3 cycles chemotherapy instead of 6 cycles chemotherapy/ 6 cycles chemotherapy**

Inclusion Criteria:
Signed written informed consent obtained prior to initiation of any study-specific procedures and treatment as confirmation of the patients awareness and willingness to comply with the study requirements. / Female patients who are at least 18 years of age on the day signing informed consent / Histologically confirmed locally advanced, recurrent, persistent and/or metastatic VSCC not amenable for salvage surgery or definitive (chemo)radiation (additive palliative radiotherapy for symptom control is allowed) / ≤2 previous lines of chemotherapy for recurrent or metastatic disease / Measurable disease (investigator assessed RECIST 1.1). Lesions situated in a previously irradiated area are considered measurable if progression has been demonstrated in such lesions. / Have an eastern cooperative oncology group (ECOG) performance status of 0-1. Evaluation of ECOG is to be performed within 7 days prior to the first dose of study intervention. / No pregnancy (as documented by a positive beta-human chorionic gonadotropin [ß-hCG] or human chorionic gonadotropin [hCG]) test with a minimum sensitivity of 25 IU/L or equivalent units of ß-hCG [or hCG]), no breastfeeding, and at least one of the following conditions applies: / Not a woman of childbearing potential (WOCBP) as defined in Appendix 4 **OR** A WOCBP who agrees to follow the contraception and pregnancy testing recommendations for investigational medicinal products (IMPs) with demonstrated or suspected human teratogenicity/ fetotoxicity in early pregnancy of the CTFG-guideline in Appendix 4 during the treatment period and for at least 4 months (corresponding to time needed to eliminate pembrolizumab) after the last dose of study treatment. In addition to the described highly effective oral/transdermal contraception methods a barrier method must be used. / A WOCBP should not become pregnant during the treatment and for at least four months. / Available archival tumor tissue sample and/or newly obtained core or excisional biopsy of a tumor lesion ideally not previously irradiated. Formalin-fixed, paraffin embedded (FFPE) tissue blocks are preferred to slides. / Adequate organ function as defined in Table 3 of study protocol. Specimens must be collected within 10 days prior to the start of study treatment.
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT05460000

Study Test Center	PI / SC	Phone	E-Mail
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A Phase II Randomized, Open Label Non-inferiority Study of NiraParib Maintenance After 3 vs. 6 Cycles of Platinum-based Chemotherapy in completeLy debUlked Advanced HRDpositive High-grade Ovarian Cancer patientS in First Line Therapy (N-Plus)

Condition: Ovarian Cancer/ Fallopian Tube Cancer/ Primary Peritoneal Carcinoma/ Clear Cell Carcinoma
Primary Completion Date: 2032-10-01
Phase: II
Intervention/ Treatment: DRUG: **Pembrolizumab/ Lenvatinib**

Inclusion Criteria:
Written informed consent and obtained from the subject prior to performing any protocol-related procedures, including screening evaluations. / Female patient, age ≥ 18 years. / FIGO Stage III-IV high-grade ovarian cancer (all histological types, except mucinous histology) / Complete primary debulked patients (without any macroscopic residuals), confirmed by CT-Scan postoperatively. / Patients must have formalin-fixed, paraffin-embedded tumor samples available from the primary cancer for central NGS analysis and must be HRDpositive defined as BRCAmut independent of NOGGO GIS Score OR NOGGO GIS Score >83 independent of BRCA status, based on these results. / Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1. / Patients must be able to take oral medications. / Synchronous and secondary malignancies are allowed if the prognosis of the ovarian cancer is not affected. The investigator must contact the medical monitoring team before enrolling the patient in the clinical trial. / Patients must have normal organ and bone marrow function: Hemoglobin ≥ 10.0 g/dL independent of transfusion ≤ 14 days prior to screening hemoglobin assessment / Absolute neutrophil count (ANC) ≥ 1.5 x 109/L / Platelet count ≥ 100 x 109/L / Total bilirubin ≤ 1.5 x institutional upper limit of normal (ULN); < 2 × ULN if hyperbilirubinemia is due to Gilbert's syndrome / Aspartate aminotransferase /Serum Glutamic Oxaloacetic Transaminase (ASAT/SGOT)) and Alanine aminotransferase /Serum Glutamic Pyruvate Transaminase (ALAT/SGPT)) ≤ 2,5 x ULN / Serum creatinine ≤ 1.5 x institutional ULN and creatinine clearance > 30 mL/min. / Postmenopausal or evidence of non-childbearing status for women of childbearing potential prior to the first dose of study treatment. Female patients of childbearing potential must have a negative serum pregnancy test result ≤3 days prior to administration of the first dose of study treatment. / Patients are considered to be of childbearing potential unless 1 of the following applies: / Considered to be permanently sterile. Permanent sterilization includes hysterectomy, bilateral salpingectomy, and/or bilateral oophorectomy; **or** Is postmenopausal, defined as no menses for at least 12 months without an alternative medical cause. A high follicle-stimulating hormone (FSH) level consistently in the postmenopausal range (30 mIU/mL or higher) may be used to confirm a postmenopausal state in women not using hormonal contraception or hormonal replacement therapy; however, in the absence of 12 months of amenorrhea, a single FSH measurement is insufficient to confirm a postmenopausal state. / Female patients of reproductive potential must practice highly effective methods (failure rate < 1% per year) of contraception with their partners, if of reproductive potential, during treatment and for 6 months following the last dose of chemotherapy or the last dose of niraparib, whichever occurs later, or longer if requested by local authorities. Highly effective contraception includes: Ongoing use of progesterone only injectable or implantable contraceptives; Placement of an intrauterine device (IUD) or intrauterine system (IUS); Bilateral tubal occlusion; Sexual abstinence as defined as complete or true abstinence, acceptable only when it is the usual and preferred lifestyle of the patient; periodic abstinence (e.g., calendar, symptothermal, post-ovulation methods) is not acceptable; or Sterilization of the male partner, with appropriate post-vasectomy documentation of absence of sperm in ejaculate.

Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT05903833

Study Test Center	PI / SC	Phone	E-Mail
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Germ Cell tumors

continue...

Contact at UCC Hamburg
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Prof Dr. med. Carsten Bokemeyer, Tel.: 040 7410-52960

Phase I/IIa, First-in-human (FIH), Open-label, Dose Escalation Trial With Expansion Cohorts to Evaluate Safety and Preliminary Efficacy of CLDN6 CAR-T With or Without CLDN6 RNA-LPX in Patients With CLDN6-positive Relapsed or Refractory Advanced Solid Tumors

Condition: Solid Tumor
Primary Completion Date: 2027-01
Phase: I/II
Intervention/ Treatment: BIOLOGICAL: **CLDN6 CAR-T/ CLDN6 uRNA-LPX/CLDN6 modRNA-LPX**

Inclusion Criteria:
Each patient enrolled in the trial must have CLDN6-positive tumor regardless of tumor histology defined as ≥ 50% of tumor cells expressing ≥ 2+ CLDN6 protein using a semi-quantitative immunohistochemistry (IHC) assay in a central laboratory for specific detection of CLDN6 protein expression in formalin-fixed, paraffin-embedded (FFPE) neoplastic tissues. /
Availability of a FFPE tumor tissue sample. FFPE can be from an archival tumor tissue sample, and it should be from the most recent tumor tissue obtained. If this is not available, patient must be biopsied for CLDN6 staining. / Must have histological documentation of the original primary tumor via a pathology report. / Must have measurable disease per RECIST 1.1 (except for germ cell tumors, where patients can be evaluated according to cancer-Antigen (CA)-125, Alpha-fetoprotein or human chorionic gonadotropin [as applicable] or ovarian cancer, where patients can be evaluated according to CA-125. The pre-treatment sample must be at least twice the upper limit of normal). / Must have a histologically confirmed solid tumor that is metastatic or unresectable and for which there is no available standard therapy likely to confer clinical benefit, or patient who is not a candidate for such available therapy. / Must be ≥ 18 years of age at the time the pre-screening informed consent is signed. /
Must sign an informed consent form (ICF) indicating that he or she understands the purpose of and procedures required for the trial and are willing to participate in the trial prior to any trial-related assessments or procedures. / Must have an Eastern Cooperative Oncology Group performance status of 0 to 1. / Must have adequate coagulation function at screening as defined in the protocol. / Must have adequate hematologic function at screening as defined in the protocol. / Must have adequate hepatic function at screening as defined in the protocol. / Must have adequate renal function at screening as defined in the protocol. / Must be able to attend trial visits as required by the protocol. / Women of childbearing potential (WOCBP) must have a negative serum (beta-human chorionic gonadotropin) test/value at screening. Patients who are post-menopausal or permanently sterilized can be considered as not having reproductive potential. / WOCBP must agree not to donate eggs (ova, oocytes) for the purposes of assisted reproduction during the entire trial and thereafter. / WOCBP and men that are sexually active with a WOCBP and have not had a vasectomy must agree to use highly effective birth control method(s), as defined in the protocol. True abstinence is an acceptable alternative to the use of contraception. / Men must agree not to father a child or donate sperm, and WOCBP must agree not to become pregnant during the trial and for at least 12 months after the CLDN6 CAR-T infusion or CLDN6 RNA-LPX treatment. / **For Part 2 only:** Histologically or cytologically confirmed solid tumor fulfilling inclusion criteria 1-4 that is metastatic or unresectable, and for whom there is no available standard therapy likely to confer clinical benefit, or patient who is not a candidate for such available therapy.
see Link:

clinicaltrials.gov/NCT04503278

Study Test Center	PI / SC	Phone	E-Mail
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Sarcomas

continue...

Contact at UCC Hamburg
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International Euro Ewing Trial For Treatment Optimisation In Patients With Ewing Sarcoma

Condition: Ewing Sarcoma
Primary Completion Date: /
Phase: III
Intervention/ Treatment: DRUG: **Vincristin Sulfate/ Doxorubicin Hydrochloride/ Cyclophosphamide/ Ifosamide/ Etoposide/ Vinorelbine**

Inclusion Criteria:
Histologically (and molecularly) diagnosed primary localised (SR) or metastatic (HR) Ewing sarcoma or so called Ewing-like sarcoma (i.e. translocation-positive small blue round cell sarcoma other than Rhabdomyosarcoma) of bone and / or soft tissue; pathological diagnosis can be performed at the investigational site / Any sex / age >2 and < 50 years by the date of diagnostic biopsy / Informed consent must be obtained according to national and GCP guidelines and signed prior to trial entry. Subjects and when applicable parental or legal representative(s) must understand and voluntarily provide permission to the ICF, prior to conducting any trial-related assessments / procedures. Willingness and ability to comply with scheduled visits and trial procedures are required. / White blood cell (WBC) count > 2000/µl* / • Assessment of cardiac function including LVEF > 40% and SF > 28%* / Serum creatinine < 1.5 X ULN* / For patients of childbearing potential, a negative pregnancy test must be documented prior to enrolment and repeated every month during therapy. Female and male patients, who are fertile and sexually active, must agree to use an effective form of contraception from the time of signing the ICF until 6 months after the end of treatment. / *Parameters must be checked within the screening phase of 45 days from biopsy biopsy / surgery and after diagnosis of metastatic disease to registration.

Exclusion Criteria:
Treatment of more than one cycle of chemotherapy prior to registration in the SR group /• Concurrent treatment within any other clinical trials, excluding trials with different endpoints, which, due to the nature of their endpoints, must run parallel to iEuroEwing trial, e.g. studies on antiemetics, antimycotics, antibiotics, strategies for psychosocial support, etc. / Clinically significant and uncontrolled, or active cardiac disease /• Evidence of invasive fungal infection or other severe systemic infection requiring systemic / parenteral therapy / Hypersensitivity to the active substance or other excipients contained in the investigational medical products listed in the summary of product characteristics (SmPC) or investigators brochure (IB). / Secondary malignancy / Pregnancy or lactation / Female and male subjects with child-bearing potential, who avoid using highly effective contraceptive methods / Any other medical, psychiatric, or social condition which is incompatible with the protocol treatment / Contraindications according to the respective applicable SmPCs / **Additional exclusion criteria iEuroEwing-SR-RT part:** Primary diagnosed and histologically confirmed metastatic (HR) Ewing sarcoma or Ewing-like sarcoma of bone and/or soft tissue / Patients who receive preoperative RTX / Patients who receive Brachytherapy / Patients who have been diagnosed with pleural effusion / Patients with previous RT in the same region
see Link:

clinicaltrialsregister.eu/2019-004153-93

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
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SARCVAC - RANDOMIZED CONTROLLED STUDY TO EVALUATE WOUND MANAGEMENT IN SARCOMA SURGERY

Condition: soft tissue sarcomas
Estimated Completion Date: /
Phase: N/A
Intervention/ Treatment: SURGICAL: **Vacuum dressing and, after 3-5 days, secondary closure vs. primary skin suture or staple suture and insertion of a Redon drain.**

Inclusion Criteria:
Patients undergoing resection of soft tissue sarcomas of the lower extremity and groin may be included in the study. Additional inclusion criteria should be met : / Patients must be over 18 years of age / Patients of any gender and origin may be included. / Maximum tumor diameter of at least 5 cm on imaging (all included patients require preoperative imaging to determine the extent of the tumor) / Location of the sarcoma on the lower extremity or groin / Treatment at a certified sarcoma center / Preoperative discussion in an interdisciplinary tumor board- Informed consent to participate in the study
Exclusion criteria:
Patients with small (<5 cm), superficial space-occupying lesions / Patients with local recurrence and pre-existing wound healing disorders in the surgical area / Ulcerated, infected tumors or emergency surgeries / Other soft tissue tumors on the skin such as Kaposi's sarcoma- Patients for whom direct closure is not possible due to the size of the resection in the firstsurgery
see Link:

Drks.de: 00036065

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Ivosidenib in Participants With Locally Advanced or Metastatic Conventional Chondrosarcoma Untreated or Previously Treated With 1 Systemic Treatment Regimen (CHONQUER)

Condition: Locally Advanced or Metastatic Conventional Chondrosarcoma With an IDH1 Mutation, Untreated or Previously Treated With 1 Systemic Treatment Regimen
Estimated Completion Date: 2028-02-01
Phase: III
Intervention/ Treatment: DRUG **Ivosidenib 500mg/ Placebo**

Inclusion Criteria:
Patients undergoing resection of soft tissue sarcomas of the lower extremity and groin may be included in the study. Additional inclusion criteria should be met : / Patients must be over 18 years of age / Patients of any gender and origin may be included. / Maximum tumor diameter of at least 5 cm on imaging (all included patients require preoperative imaging to determine the extent of the tumor) / Location of the sarcoma on the lower extremity or groin / Treatment at a certified sarcoma center / Preoperative discussion in an interdisciplinary tumor board- Informed consent to participate in the study
Exclusion criteria:
Patients with small (<5 cm), superficial space-occupying lesions / Patients with local recurrence and pre-existing wound healing disorders in the surgical area / Ulcerated, infected tumors or emergency surgeries / Other soft tissue tumors on the skin such as Kaposi's sarcoma- Patients for whom direct closure is not possible due to the size of the resection in the firstsurgery
see Link:

www.CHONQUER.com

clinicaltrials.gov/NCT06127407

Study Test Center	PI / SC	Phone	E-Mail
UKE Medical Oncology	Dr. med. Jana Käthe Striefler Laura Philine Schmidt (SC)	040-7410-55692 0152 28801854	j.striefler@uke.de LauraPhiline.Schmidt@uke.de

Phase III Study Comparing Trabectedin (T) Versus T Plus tTF-NGR to Entrap T Inside the Tumor in Patients With Metastatic and/or Refractory Soft Tissue Sarcoma (STS)

Condition: Soft Tissue Sarcoma
Estimated Completion Date: 2026-08
Phase: III
•**Intervention/ Treatment:** DRUG **Trabectedin**_BIOLOGICAL: **tTF-NGR**

Inclusion Criteria:
Patients of all genders (female, male, diverse), with no restriction regarding ethnic or religious background age 18 - 75 years. / Patients with advanced or metastatic soft-tissue sarcoma after failure of anthracycline-containing first line therapy (or anthracycline-containing adjuvant therapy within 12 months before entry on study) or with contraindications to these drugs / Patients must have histological evidence of high-grade advanced unresectable or metastatic soft tissue sarcoma (grade 2 - 3) according to the FNCLCC grading system. **The following tumor types are included:** / Dedifferentiated liposarcoma / Myxoid liposarcoma (high grade) / Pleomorphic liposarcoma / Adult fibrosarcoma / Myxofibrosarcoma (high-grade) / Leiomyosarcoma / Rhabdomyosarcoma (alveolar, pleomorphic) / Angiosarcoma / Synovial sarcoma / Undifferentiated sarcoma / / Tumor types not listed above may be included upon communication with Coordinating Investigator. / **The following tumor types will not be included:** / Gastrointestinal stromal tumors (GIST) / Epitheloid sarcoma / Alveolar soft part sarcoma / Desmoplastic small round cell tumor / Chondrosarcoma / Osteosarcoma / Ewing sarcoma (including CIC-rearranged sarcoma and Sarcoma with BCOR alterations) / / CD13 positivity with a score of ≥ 1 (20) by central pathology (GDI Münster) / Patients must have at least one unidimensionally measurable lesion by computed tomography as defined by RECIST criteria 1.1. Other adequate imaging procedures such as MRI are allowed. This lesion should not have been irradiated during previous treatments 1.Life expectancy of at least 3 months / Eastern Cooperative Oncology Group (ECOG) Performance Status ≤ 2 / No contraindications for trabectedin (see attachment) / Negative serum pregnancy test for females of childbearing potential* within 14 days of starting treatment / Informed consent signed and dated to participate in the study / Willingness and ability to comply with the scheduled visits, treatment plan, laboratory tests and other study procedures / Women of childbearing potential (WOCBP) must be using, from the screening to 3 months following the last trabectedin (Arm 1) or the last last study drug (Arm 2) administration, highly effective contraception methods, as defined by the "Recommendations for contraception and pregnancy testing in clinical trials" issued by the Head of Medicine Agencies' Clinical Trial Facilitation Group (www.hma.eu/ctfg.html) and which include, for instance, progesteron-only or combined (estrogen- and progesteron-containing) hormonal contraception associated with inhibition of ovulation, intrauterine devices, intrauterine hormone-releasing systems, bilateral tubal occlusion, vasectomized partner or sexual abstinence. Pregnancy test will be repeated monthly. For men contraception methods should be performed for 5 months after the last application of trabectedin (Arm1) or study drug (Arm 2).Women of childbearing potential are defined as females who have experienced menarche, are not postmenopausal (12 months with no menses without an alternative medical cause) and are not permanently sterilized (e.g., tubal occlusion, hysterectomy, bilateral oophorectomy or bilateral salpingectomy)
Exclusion criteria:
see Link:

clinicaltrials.gov/NCT05597917

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Hepatocellular carcinomas

continue...

Contact at UCC Hamburg
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A Phase II Study of Immunotherapy With Durvalumab (MEDI4736) and Tremelimumab in Combination With Y-90 SIRT for Intermediate Stage HCC

Condition: Hepatocellular Carcinoma Non-resectable, HCC
Primary Completion Date: N/A
Phase: II
Intervention/ Treatment: DRUG: **Tremelimumab/ Durvalumab**_PROCEDURE: **Y-90 SIRT/ DEB-TACE**

Inclusion Criteria:
Capable of giving written informed consent and any locally-required authorization (EU Data Privacy Directive in the EU) obtained from the subject prior to performing any protocol-related procedures, including screening evaluations. / Age ≥ 18 years at time of study entry. / Body weight > 30 kg. / Multinodular or large, solitary HCC, not eligible for resection or local ablation. / Histologically confirmed diagnosis of HCC. / Scheduled to receive locoregional therapy as standard of care. / At least one measurable site of disease as defined by RECIST 1.1criteria with spiral CT scan or MRI. / No prior systemic anti-cancer therapy. / Child-Pugh A. / Performance status (PS) ≤ 1 (ECOG scale). / Life expectancy of at least 12 weeks. / Adequate blood count, liver-enzymes, and renal function: / Hemoglobin ≥ 9.0 g/dL, absolute neutrophil count ANC ≥1.5 (or 1.0) x (> 1500 per mm^3), platelets ≥100 (or 75) x 10^9/L (>75,000 per mm^3); / Serum bilirubin ≤1.5 x institutional upper limit of normal (ULN); / AST (SGOT), ALT (SGPT) ≤ 2.5 x institutional ULN unless liver metastases are present, in which case it must be ≤5x ULN; / International normalized ratio (INR) ≤ 1.25. / Albumin ≥ 31 g/dL. / Measured creatinine clearance (CL) >40 mL/min or Calculated creatinine clearance CL>40 mL/min by the Cockcroft-Gault formula (Cockcroft and Gault 1976) or by 24-hour urine collection for determination of creatinine clearance.
1.Female patients with reproductive potential must have a negative urine or serum pregnancy test within 7 days prior to start of trial and must use two effective forms of contraception if sexually active.
2.Men who are sexually active with WOCBP must use any contraceptive method with a failure rate of less than 1% per year. Men receiving IMP and who are sexually active with WOCBP will be instructed to adhere to contraception for a period of 7 months after the last dose of investigational products (Durvalumab and Tremelimumab). Women who are not of childbearing potential (i.e. who are postmenopausal or surgically sterile) as well as azoospermic men do not require contraception). / If patient has concurrent Hepatitis B virus (HBV) or Hepatitis C virus (HCV) infection, **meets the following criteria:** Patients with HBV or HCV infection should be monitored for viral levels during study participation; / Patients with detectable hepatitis B surface antigen (HBsAg) or detectable HBV DNA should have HBV DNA < 100 IU/ml and should be managed per local treatment guidelines. Controlled (treated) hepatitis B subjects will be allowed if they started treatment at the time point of enrollment into the study by the latest and treatment is continued during study participation and for ≥ 6 months after end of study treatment; / HCV patients with advanced HCC are mostly not treated for their HCV infection. However, patients treated for HCV are considered suitable for inclusion if antiviral therapy has been completed prior to first administration of study drug.
3.Subject is willing and able to comply with the protocol for the duration of the study including
•**Exclusion criteria**:
see Link:

clinicaltrials.gov/NCT04522544

Study Test Center	PI / SC	Phone	E-Mail
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The ABC-HCC Trial: A Phase IIIb, Randomized, Multicenter, Open-label Trial of Atezolizumab Plus Bevacizumab Versus Transarterial Chemoembolization (TACE) in Intermediate-stage HepatoCellular Carcinoma

Condition: Hepatocellular Carcinoma
Primary Completion Date: 2027-07
Phase: III
Intervention/ Treatment: DRUG: **Atezolizumab/Bevacicumab** _PROCEDURE: **TACE**

Inclusion Criteria:

Signed Informed Consent Form available / Patients* ≥ 18 years of age at time of signing Informed Consent Form / Confirmed hepatocellular carcinoma diagnosis based on histopathological findings from tumor tissue or typical diagnostic imaging on dynamic CT or MRI according to AASLD criteria. / Intermediate stage HCC as defined by the **following criteria:** Disease not amenable to curative surgery, liver transplantation or curative ablation BUT disease amenable to TACE at enrollment as judged by the investigator. / No massive multinodular pattern preventing adequate TACE / No tumor of a diffuse infiltrative HCC type (hypovascular infiltrative tumors with ill-defined borders) / Patent portal vein flow / No main portal vein invasion/thrombosis on baseline/eligibility imaging. Patients with minimal invasion, (Vp1 and Vp2) may be eligible if no exclusion criteria are violated. / No extrahepatic disease Note: Patients with HCC beyond Milan criteria who enter a downstaging protocol may be recruited into the trial if they do not present any exclusion criteria. / Patients with recurrence after resection/ablation or after previous TACE are eligible, if they - according to the investigator - have an indication for (additional) TACE
1.Child-Pugh score class A or B7 without ascites requiring more than 100 mg of spironolactone/day (see exclusion criteria) at enrollment. / Eastern Cooperative Oncology Group (ECOG) performance status of 0-1 at enrollment. / Adequate organ and bone marrow function / Life expectancy of ≥ 3 months / The **following laboratory values** obtained less than or equal to 7 days prior to randomization. Total bilirubin ≤ 3.0 x the upper limit of normal (ULN) / Urine dipstick for proteinuria ≤ 2+ (within 7 days prior to randomization) Patients discovered to have ≥ 2+ proteinuria on dipstick urinalysis at baseline should undergo a 24-hour urine collection and must demonstrate < 1 g of protein in 24 hours / The following other laboratory values measured within 7 days prior to randomization are either normal or if abnormal do not represent a medical contraindication for TACE and atezolizumab/bevacizumab as judged by the investigator: Platelet count, hemoglobin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), serum creatinine, INR or aPTT, alkaline phosphatase, neutrophil count (ANC), and serum albumin. / Negative serum pregnancy test done lesser than or equal to 7 days prior to randomization, for females of childbearing potential only. / No presence of untreated or incompletely treated varices with bleeding or high-risk for bleeding: Availability of esophagogastroduodenoscopy (not older than 6 months) in which all size of varices (small to large) had been assessed and varices were treated per local standard of care prior to randomization. / Absence of other severe comorbidities / Resolution of any acute, clinically significant treatment-related adverse events from prior therapy/procedure to Grade ≤ 1 prior to randomization, with the exception of alopecia. / For patients with active hepatitis B virus (HBV): / HBV DNA ≤ 2000 IU/mL obtained within 28 days prior to randomization, **AND** Anti-HBV treatment (per local standard of care; e.g., entecavir) for a minimum of 14 days prior to randomization and willingness to continue treatment for the length of the study. / **For patients with active hepatitis C virus (HCV):** Patients positive for hepatitis C virus (HCV) antibody are eligible, also if polymerase chain reaction testing is positive for HCV ribonucleic acid (RNA). / However, anti-viral therapy against HCV is only allowed prior to trial but not during the trial. / For HBV and HCV co-infection refer to exclusion criterion # 11. / For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods with a failure rate of < 1% per year during the treatment period and for at least 5 months after the last dose of atezolizumab, 6 months after the last dose of bevacizumab, or 1 month after the last TACE procedure. / A woman is considered to be of childbearing potential if she is postmenarcheal, has not reached a postmenopausal state (≥12 continuous months of amenorrhea with no identified cause other than menopause), and has not undergone surgical sterilization (removal of ovaries and/or uterus). / Examples of contraceptive methods with a failure rate of < 1% per year include bilateral tubal ligation, male sterilization, hormonal contraceptives that inhibit ovulation, hormone-releasing intrauterine devices, and copper intrauterine devices. / The reliability of sexual abstinence should be evaluated in relation to the duration of the clinical trial and the preferred and usual lifestyle of the patient. Periodic abstinence (e.g., calendar, ovulation, symptothermal, or postovulation methods) and withdrawal are not acceptable methods of contraception. / For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating sperm, as defined below: / With female partners of childbearing potential, men must remain abstinent or use a condom plus an additional contraceptive method that together result in a failure rate of < 1% per year during the treatment period and for 6 months after the last dose of bevacizumab or 1 month after the last TACE procedure. Men must refrain from donating sperm during this same period. / With pregnant female partners, men must remain abstinent or use a condom during the treatment period and for 6 months after the last dose of bevacizumab or 1 month after the last TACE procedure to avoid exposing the embryo. / The reliability of sexual abstinence should be evaluated in relation to the duration of the clinical trial and the preferred and usual lifestyle of the patient. Periodic abstinence (e.g., calendar, ovulation, symptothermal, or postovulation methods) and withdrawal are not acceptable methods of contraception. / There are no data that indicate special gender distribution. Therefore, patients will be enrolled in the study gender-independently.

•Exclusion criteria:

see Link:

clinicaltrials.gov/NCT04803994

Study Test Center	PI / SC	Phone	E-Mail
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Renal cell carcinoma

continue...

Contact at UCC Hamburg
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A Phase 3, Randomized, Open-label Study of Belzutifan + Zanzalintinib Versus Cabozantinib in Participants With Advanced RCC Who Experienced Disease Recurrence During or After Prior Adjuvant Anti-PD-1/L1 Therapy (LITESPARK-033)

Condition: Renal Cell Carcinoma
Primary Completion Date: 2032-02-27
Phase: III
Intervention/ Treatment: DRUG: **Belzutifan/ Zanzalintrinib/ Cabozantinib**

Inclusion Criteria:
Has a histologically confirmed diagnosis of unresectable, advanced renal cell cancer (RCC) with clear cell component (with or without sarcomatoid features) i.e., Stage IV renal cell cancer per American Joint Committee on Cancer (AJCC) (8th Edition) / Has measurable disease per Response Evaluation Criteria in Solid Tumors 1.1 (RECIST 1.1) / Has disease recurrence during adjuvant anti-programmed cell death 1/programmed cell death ligand 1 (PD-1/L1) therapy or recurrence ≤24 months following the last dose of adjuvant anti-PD-1/L1 therapy / Has received no other prior systemic therapy for their RCC except for their adjuvant anti-PD-1/L1 therapy

Exclusion Criteria:
Has clinically significant cardiovascular disease within 12 months from first dose of study intervention, including New York Heart Association Class III or IV congestive heart failure, unstable angina, new-onset angina, pulmonary embolism, myocardial infarction, cerebral vascular accident, or cardiac arrhythmia associated with hemodynamic instability / Had deep vein thrombosis within 3 months before randomization unless stable, asymptomatic, and treated with therapeutic anticoagulation for at least 4 weeks before randomization / Has a left ventricular ejection fraction ≤50% or below the institutional (or local laboratory) normal range as determined by multigated acquisition or echocardiogram / Has had major surgery within 8 weeks before randomization or has not adequately recovered from major surgery or has ongoing surgical complications / Has current pneumonitis/interstitial lung disease / Has symptomatic pleural effusion (for example cough, dyspnea, pleuritic chest pain), ascites, or pericardial fluid requiring drainage within 4 weeks prior to randomization / Has a gastrointestinal disorder including those associated with a high risk of perforation or fistula formation / Has a serious active nonhealing wound/ulcer/bone fracture / Has a requirement for hemodialysis or peritoneal dialysis / Has history of human immunodeficiency virus infection / Has hepatitis B or hepatitis C virus / Received a live or live-attenuated vaccine within 30 days before the first dose of study intervention

see Link:

clinicaltrials.gov/NCT07227402

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
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Skin tumors

18a ***Melanoma***

18b ***Other Neoplasms Skin***

18c ***(Uveal Melanoma)***

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Melanoma

continue...

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Phase 2/3 Randomized Study of Tebentafusp as Monotherapy and in Combination With Pembrolizumab Versus Investigator's Choice in HLA-A*02:01-positive Participants With Previously Treated Advanced Melanoma

Condition: Advanced Melanoma
Primary Completion Date: 2035-12
Phase: II/III
Intervention/ Treatment: DRUG: **EIK1001-006/ Pembrolizumab (KEYTRUDA)**

Inclusion Criteria:
Be ≥ 18 years of age on the day of signing of informed consent. / Have a life expectancy of at least 3 months. / Have histologically or cytologically confirmed Stage 3 (unresectable) or Stage 4 metastatic melanoma per AJCC 8th ed. and be eligible for standard therapy with pembrolizumab. / Have at least 1 lesion with measurable disease at Baseline by CT or MRI according to Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 by assessment of local site Investigator/radiologist. / Have known BRAF V600 mutation status or consent to BRAF V600 mutation testing per local institutional standards during the screening period / Have completed prior radiotherapy at least 2 weeks prior to study treatment administration. / Have an ECOG Performance Status of 0 to 1. / Have adequate organ and marrow function as defined by normal CBC, coagulation, serum chemistry and liver function tests on specimens collected within 10 days of treatment start. / Have a negative serum pregnancy test within 72 hours prior to receiving the first dose of study medication (applies to women of childbearing potential [WOCBP]). / Be willing to use either 2 adequate methods of contraception, 1 adequate method plus a hormonal method of contraception, or be willing to abstain from heterosexual activity throughout the study (Visit 1 to 120 days after the last dose of study therapy; applies to WOCBP who are not menopausal for > 2 years, post-hysterectomy/oophorectomy, or surgically sterilized). / Agree to use an approved adequate contraceptive method throughout the study (Visit 1 to 120 days after the last dose of study therapy; applies to sexually active male participants with a partner who is WOCBP). / Be willing and able to provide written, informed consent for the study.

Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT06697301

Study Test Center	PI / SC	Phone	E-Mail
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UKSH Kiel Dermatology	PD Dr. med. Katharina Kähler Frauke Westermann (SC)	0431 500 21131 0431 500 21131	Katharina.Kaehler@uksh.de Frauke.Westermann@uksh.de

Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Phase 2/3 Randomized Study of Tebentafusp as Monotherapy and in Combination With Pembrolizumab Versus Investigator's Choice in HLA-A*02:01-positive Participants With Previously Treated Advanced Melanoma

Condition: Advanced Melanoma
Primary Completion Date: 2026-12
Phase: II/III
Intervention/ Treatment: DRUG: **Tebentafusp/ Tebentafusp with Pembrolizumab/ Investigators Choice**

Inclusion Criteria:
HLA-A*02:01-positive. / unresectable Stage III or Stage IV non-ocular melanoma / archival tumor tissue sample or a newly obtained biopsy of a tumor lesion not previously irradiated has been provided. measurable or non-measurable disease per RECIST 1.1 / Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1 / If applicable, must agree to use highly effective contraception / Capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the Informed Consent (ICF) and protocol /
Must agree to provide protocol specified samples for biomarker analyses.

Exclusion Criteria:
Pregnant or lactating women / diagnosis of ocular or metastatic uveal melanoma / history of a malignant disease other than those being treated in this study / ineligible to be retreated with pembrolizumab due to a treatment-related AE / known untreated or symptomatic central nervous system (CNS) metastases and/or carcinomatous meningitis / previous severe hypersensitivity reaction to treatment with another monoclonal antibody (mAb) / active autoimmune disease requiring immunosuppressive treatment with clinically significant cardiac disease or impaired cardiac function / known psychiatric or substance abuse disorders / received prior treatment with a licensed or investigative Immune-mobilizing monoclonal T-cell receptor Against cancer (ImmTAC) medication who have not completed adequate washout from prior medications. / received chemotherapy or biological cancer therapy (excluding anti-PD(L)1 mAb, ipilimumab, and BRAF TKI regimen) within 14 days of first dose / received cellular therapies within 90 days of study intervention / ongoing Common Terminology Criteria for Adverse Events(CTCAE) Grade ≥ 2 clinically significant who in the opinion of the investigator could affect the outcome of the study / received systemic treatment with steroids or any other immunosuppressive drug within 2 weeks of first dose / have not progressed on treatment with an anti-PD(L)1 mAb /
have not received prior ipilimumab / a BRAF V600 mutation, who have not received a prior BRAF/MEK TKI regimen / currently participating or have participated in a study of an investigational agent or using an investigational device within 30 days of the first dose / known history of chronic viral infections such as hepatitis B virus (HBV) or hepatitis C virus (HCV) / Out of range Laboratory values /
history of allogenic tissue/solid organ transplant
see Link:

clinicaltrials.gov/NCT05549297

Study Test Center	PI / SC	Phone	E-Mail
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Hämatolisch-Onkologische Praxis Eppendorf	Prof. Dr. med. Alexander Stein Dr. med. Eray Gökkurt	040-360352222	stein@hope-hamburg.de goekkurt@hope-hamburg.de

Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

This is a phase 3, randomized, controlled study of IMC-F106C plus nivolumab compared to standard nivolumab regimens in HLA-A*02:01-positive participants with previously untreated advanced melanoma.

Condition: Advanced Melanoma
Primary Completion Date: 2026-12-01
Phase: III
Intervention/ Treatment: BIOLOGICAL: **IMC-F106C/ Nivolumab/ Nivolumab + Relatlimab**

Inclusion Criteria:
Participants must be HLA-A*02:01-positive / Participants must have histologically confirmed Stage IV or unresectable Stage III melanoma / Archived or fresh tumor tissue sample that must be confirmed as adequate / Participants must have measurable disease per RECIST 1.1 / Participant must have BRAF V600 mutation status determined / Participants must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1 / Male and female participants of childbearing potential who are sexually active with a non-sterilized partner must agree to use highly effective methods of birth control from the study screening date until 5 months after the final dose of study intervention

Exclusion Criteria:
Participants with a history of a malignant disease other than those being treated in this study / Participants with untreated, active, or symptomatic central nervous system (CNS) metastases or carcinomatous meningitis / Hypersensitivity to IMC-F106C, nivolumab, relatlimab, or any associated excipients / Participants with clinically significant pulmonary disease or impaired lung function / Participants with clinically significant cardiac disease or impaired cardiac function / Participants with active autoimmune disease requiring immunosuppressive treatment / Participants with any medical condition that is poorly controlled or that would, in the Investigator's or Sponsor's judgment, adversely impact the participant's participation in the clinical study due to safety concerns, compliance with clinical study procedures, or interpretation of study results / Participants who received prior systemic anticancer therapy for unresectable or metastatic melanoma / Participants with a history of a life-threatening AE related to prior anti-PD-(L)1 or anti-LAG-3

see Link:

clinicaltrials.gov/NCT06112314

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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Phase 3, Multicenter, Randomized, Open-label, Parallel Group, Treatment Study to Assess the Efficacy and Safety of the Lifileucel (LN-144, Autologous Tumor Infiltrating Lymphocytes [TIL]) Regimen in Combination With Pembrolizumab Compared With Pembrolizumab Monotherapy in Participants With Untreated, Unresectable or Metastatic Melanoma

Condition: Metastatic Melanoma, Unresectable Melanoma, Melanoma
Primary Completion Date: 2028-03-01
Phase: III
Intervention/ Treatment: BIOLOGICAL: **Lifileucel plus Pembrolizumab/ Pembrolizumab with Optional Crossover Period**

Inclusion Criteria:
Participant has a histologically or pathologically confirmed diagnosis of Stage IIIC, IIID, or IV unresectable or metastatic melanoma. / In the investigator's assessment, the participant has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 and an estimated life expectancy of > 6 months. / Participant is assessed as having at least one resectable lesion (or aggregate lesions) for lifileucel generation. / Participant must have at least one measurable disease as defined by RECIST 1.1 following tumor resection. / Participants must have adequate organ function. / Participants of childbearing potential or those with partners of childbearing potential must be willing to practice an approved method of highly effective birth control. / Participants who are > 70 years of age may be allowed to enroll after the investigator discusses with the medical monitor.

Exclusion Criteria:
Participant has melanoma of uveal/ocular origin. / Participant has symptomatic untreated brain metastases. / Participant received more than 1 prior line of therapy. / Participant received prior therapy for metastatic disease / Participants with a BRAF V600 mutation-positive tumor received prior adjuvant/neoadjuvant ICI therapy only / Participant has an active medical illness(es) that, in the opinion of the investigator, would pose increased risks for study participation, such as systemic infections; seizure disorders; coagulation disorders; or other active major medical illnesses of the cardiovascular, respiratory, or immune systems. / Participant has any form of primary or acquired immunodeficiency (eg, SCID or AIDS). / Participant had another primary malignancy within the previous 3 years (except for those that do not require treatment or were curatively treated >1 year ago, and in the judgment of the investigator do not pose a significant risk of recurrence.) / Participant has a history of allogeneic cell or organ transplant. / Other protocol defined inclusion/exclusion criteria could apply.

see Link:

clinicaltrials.gov/NCT05727904

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Universitäres Cancer Center HAMBURG
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Randomized, Ph3 Clinical Study Comparing Vusolimogene Oderparepvec in Combination With Nivolumab Vs Treatment of Physician's Choice in Patients With Advanced Melanoma That Progressed on Anti-PD-1 and Anti-CTLA-4 Containing Treatment [IGNYTE-3]

Condition: Advanced Melanoma
Primary Completion Date: 2029-01-01
Phase: III
Intervention/ Treatment: DRUG: **Single-agent chemotherapy**_BIOLOGICAL: **Vusolimogene Oderparepvec/ Nivolumab/ Nivolumab + Relatlimab/ Pembrolizumab**

Inclusion Criteria:
Male or female who is 12 years of age or older at the time of signed informed consent. / I 2. Patients with histologically or cytologically confirmed unresectable or metastatic Stage IIIb through IV/M1a through M1d cutaneous melanoma, as per AJCC staging system, 8th edition). / I 3. Confirmed disease progression (PD) on an anti-PD-1 antibody treatment and an anti-CTLA-4 antibody treatment, administered as either a combination regimen (eg, nivolumab + ipilimumab) or in sequence. / Treatment with prior anti-PD-1 therapy must have continued for a minimum of 8 weeks (note: treatment with prior pembrolizumab therapy when administered every 6 weeks must have continued for a minimum of 12 weeks [ie, 2 treatment cycles]). Any number of doses of prior anti-CTLA-4 therapy may have been administered in combination with an anti-PD-1. The anti-PD-1-containing therapy must be the immediate prior line of treatment before randomization (for patients with BRAF mutation, see I 4). / Patients who in the physician's judgement are not candidates for treatment with an anti-CTLA-4 antibody (eg, due to documented clinically significant comorbidities or history of immune-related adverse events) are eligible for the study if they have confirmed PD on an anti-PD-1 antibody (including unresectable disease relapse during adjuvant therapy or < 6 months from completion of adjuvant therapy). / Disease progression must have been confirmed and documented using clinical or radiological assessment by 2 assessments at least 4 weeks apart while being treated with an anti-PD-1 antibody and an anti-CTLA-4 antibody. Radiological confirmation of PD can occur during the Screening period for this study. Treatment with prior anti-PD-1 therapy must have continued from the time of initial tumor progression until confirmation of PD (ie, such that no doses of anti-PD-1 therapy were missed). / Note: If radiographic progression at the initial scan where PD was documented is accompanied by clear clinical progression, defined as a decline in performance status directly attributed to disease or increased disease-related symptoms, anti-PD-1 therapy does not need to continue. For patients with documented PD while on adjuvant therapy with an anti-PD-1 therapy, a confirmatory biopsy can be used in place of a confirmatory scan. / I 4. Has documented BRAF V600 mutation status or must consent to BRAF V600 mutation testing per local institutional standards during the Screening period. Patients with BRAF mutation should have received prior BRAF-directed therapy (with or without a MEK inhibitor) prior to randomization, unless deemed not clinically indicated at Investigator's discretion due to concurrent medical condition or prior toxicity. / Note: Prior exposure to BRAF-directed therapy (with or without a MEK inhibitor) includes treatment in the adjuvant setting. One line of BRAF-directed therapy (with or without a MEK inhibitor) can be the most recent systemic treatment administered before randomization. / I 5. Has least 1 measurable tumor of ≥ 1 cm in longest diameter (or shortest diameter for lymph nodes) and injectable lesion(s) of at least 1 cm in longest diameter. / I 6. Has adequate hematologic function, including: / White blood cell (WBC) count ≥ 2.0 × 109/L / Absolute neutrophil count (ANC) ≥ 1.5 × 109/L / Platelet count ≥ 75 × 109/L / Hemoglobin ≥ 8 g/dL (without packed red blood cell [RBC] transfusion within 2 weeks of dosing) / I 7. Has adequate hepatic function, including: / Total bilirubin ≤ 1.5 × upper limit of normal (ULN; < 2.0 × ULN for patients with known Gilbert syndrome or liver metastases) / Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) ≤3.0 × ULN (or ≤ 5.0 × ULN, if liver metastases are present) / Alkaline phosphatase (ALP) ≤ 2.5 × ULN (or ≤ 5.0 × ULN, if liver or bone metastases are present) I 8. Has adequate renal function, defined as serum creatinine ≤ 1.5 × ULN or creatinine clearance ≥ 3 0 mL/minute/1.73 m2 (measured using Chronic Kidney Disease Epidemiology Collaboration [CKD-EPI] formula). / I 9. Prothrombin time (PT) ≤ 1.5 × ULN (or international normalization ratio [INR] ≤ 1.3) and partial thromboplastin time (PTT) or activated partial thromboplastin time (aPTT) ≤ 1.5 × ULN. Note: Patients who are on chronic anticoagulant therapy may be randomized if the target INR is ≤ 2.5. For patients requiring deep injection of VO, the INR must be <1.5 at the time of injection. / I 10. ECOG performance status (PS) 0 to 1 for patients 18 and older or a Lansky PS ≥ 80 for patients 12 to 17 years of age. / I 11. Life expectancy of at least 3 months. I 12. Female and male patients of reproductive potential must agree to avoid becoming pregnant or impregnating a partner and adhere to highly effective contraception requirements during the treatment period and for at least 6 months after the last dose of any study treatment. / I 13. Women of childbearing potential must have a negative serum beta-human chorionic gonadotropin (β-hCG) test with a minimum sensitivity of 25 IU/L or equivalent units or β hCG within 7 days before the first dose of study treatment. I 14. Capable of giving signed informed consent which includes willingness to comply with the requirements and restrictions listed in the informed consent form (ICF)

Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT06264180

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Universitäres Cancer Center HAMBURG

Universitätsklinikum Hamburg-Eppendorf

A Phase 2 Peri-operative Trial of Fianlimab and Cemiplimab Compared With Anti-PD1 Alone in Patients With Resectable Stage III and IV Melanoma

Condition: Melanoma
Primary Completion Date: 2027-03-11
Phase: II
Intervention/ Treatment: DRUG: **Cemiplimab/ Fixed Dose Combination (FDC) Zemiplimab+Fianlimab/ Placebo**

Inclusion Criteria:
All patients must be either stage III (IIIB, IIIC, IIID) or stage IV (M1a, M1b, M1c) per American Joint Committee on Cancer (AJCC) 8th edition (Amin 2017) and have histologically confirmed cutaneous melanoma that is deemed completely surgically resectable in order to be eligible as described in the protocol. / Patients with stage III melanoma must have clinically detectable disease that is confirmed as malignant on the pathology report. The pathology report must be reviewed, signed and dated by the investigator; this process will be confirmed during the interactive voice response system (IVRS) process as described in the protocol. / Patients must be candidates for full resection with curative intent and must be able to be surgically rendered free of disease with negative margins on resected specimens at surgery. The treatment plan including date of surgery must be documented by the investigator prior to randomization. / All patients must undergo full disease staging through a complete physical examination and imaging studies within 4 weeks prior to randomization. Imaging must include a computer tomography (CT) scan of the chest, abdomen, pelvis (if the primary tumor is on the head/neck then include a CT scan of head/neck), and all known sites of previously resected disease (if applicable) and brain magnetic resonance imaging (MRI) (or brain CT with contrast allowed if MRI is contraindicated). / Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0 or 1
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT06190951

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A Phase 2, Randomized, Double-Blind, Placebo- and Active-Comparator-Controlled Clinical Study of V940 (mRNA-4157) Plus Pembrolizumab Versus Placebo Plus Pembrolizumab in Participants With First-Line Advanced Melanoma

Condition: Malignant Melanoma
Primary Completion Date: 2028-07-22
Phase: II
Intervention/ Treatment: BIOLOGICAL: **V940-012/ Pembrolizumab/ Placebo**

Inclusion Criteria:
Has unresectable and histologically confirmed Stage III or IV cutaneous melanoma per American Joint Committee on Cancer (AJCC) Eighth Edition guidelines.
Has been untreated for melanoma except if participant received prior adjuvant or neoadjuvant therapy with targeted therapy or immunotherapy (such as anti-cytotoxic T-lymphocyte-associated protein [CTLA-4], anti-programmed cell death 1 protein [PD-1] therapy or interferon), and only if relapse did not occur within 12 months after treatment discontinuation.
Have documentation of serine/threonine-protein kinase B-raf (BRAF) V600-activating mutation status or had BRAF V600 mutation testing per local institutional standards during the screening period (participants with BRAF mutation positive melanoma as well as BRAF wild-type or unknown are eligible).
Have the presence of at least 1 measurable lesion by computed tomography (CT) or magnetic resonance imaging (MRI) per Response Criteria in Solid Tumors Version 1.1 (RECIST 1.1) as determined by the local site investigator/radiology assessment.
Provides tumor tissue (preferably from a metastatic site and, if not available, from the primary tumor) that is suitable for next generation sequencing and biomarker analysis as required for this study.
Participants with human immunodeficiency virus (HIV) must have well controlled HIV on antiretroviral therapy (ART).
Participants who are hepatitis B surface antigen (HBsAg) positive are eligible if they have received hepatitis B virus (HBV) antiviral therapy for at least 4 weeks, and have undetectable HBV viral load prior to randomization.
Participants with history of hepatitis C virus (HCV) infection are eligible if HCV viral load is undetectable at screening.
Exclusion Criteria:

see Link:

clinicaltrials.gov/NCT06961006

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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Adjuvant Tebentafusp (IMCgp100) Versus Observation in HLA-A*02:01 Positive Patients Following Definitive Treatment of High-risk Uveal Melanoma: an EORTC Randomized Phase III Study (ATOM Trial)

Condition: Uveal Melanoma
Primary Completion Date: 2032-11
Phase: III
Intervention/ Treatment: DRUG: Tebentafusp

Inclusion Criteria:
Primary non-metastatic UM, except iris melanoma, after definitive treatment either by surgery or radiotherapy
Time from primary treatment smaller than 11 weeks (note that the maximum time between primary treatment and randomization is 12 weeks)
High-risk according to either 1) clinical criteria: TNM (AJCC8) stage III or 2) genetic criteria: monosomy 3 or GEP class 2. Prior to enrolment of the first patient, each site will declare which of the two genetic criteria it uses. Patients with stage I and stage II are only eligible if they meet the genetic criterion declared by the site.
ECOG performance status of 0 or 1
18 years or older
HLA-A*02:01 positivity by local assessment
No evidence of UM recurrence, as evidenced by the required baseline imaging performed within 4 weeks prior to randomization
Adequate organ function
Time-interval between the end of primary treatment and the randomization less than or equal to 12 weeks
Evidence of post-menopausal status or negative urinary or serum pregnancy test for women of childbearing potential (WOCBP) within 3 days prior to randomization.
For patients of childbearing / reproductive potential, agreement to use adequate birth control measures during the study treatment period and for at least 6 months after the last dose of treatment. A highly effective method of birth control is defined as a method which results in a low failure rate (i.e., less than 1% per year) when used consistently and correctly.
For female subjects who are breast feeding, agreement to discontinue nursing prior to the first dose of study treatment and until 6 months after the last study treatment.
Written informed consent according to ICH/GCP and local regulations
Exclusion Criteria:

clinicaltrials.gov/NCT06246149

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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

"SUPRAME", ACTengine® IMA203-301

Entities
300

A Prospective, Multicenter, Open-label, Randomized, Actively Controlled, Parallel-group Phase 3 Clinical Trial to Evaluate Efficacy, Safety, and Tolerability of IMA203 Versus Investigator's Choice of Treatment in Patients With Previously Treated, Unresectable or Metastatic Cutaneous Melanoma (ACTengine® IMA203-301)

Condition: Melanoma, Cutaneous Malignant
Primary Completion Date: 2028-01
Phase: III
Intervention/ Treatment: DRUG: **Dacarbazine/ Temozolomide/ Paclitaxel/ Paclitaxel plus carboplatin/ Albumin-Bound Paclitaxel**_BIOLOGICAL: **IMA203/ Nivolumab plus Relatlimab/ Lifileucel/ Nivolumab/ Pembrolizumab/ Ipilimumab**

Inclusion Criteria:
Pathologically confirmed and documented cutaneous melanoma- CM patients (including acral melanoma) with unresectable or metastatic disease
HLA-A*02:01 positive
Adequate selected organ function per protocol
Eastern Cooperative Oncology Group (ECOG) performance status 0-1
Disease progression (resistance, toxicity) on or after at least one PD-1 inhibitor, applied either as monotherapy or in combination with other therapies as treatment for unresectable or metastatic cutaneous melanoma
Patients with BRAF mutation should have been treated with one prior line of BRAF-directed therapy (with or without a MEK inhibitor) prior to initial eligibility assessment, unless deemed not clinically indicated at Investigator's discretion due to concurrent medical condition, prior toxicity, or if declined by the patient
Life expectancy more than 6 months
Measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST 1.1)
Female patient of childbearing potential must use adequate contraception from randomization until 12 months after the infusion of IMA203 or in line with the instructions provided for investigator's choice treatment (in the control arm)
Male patient must agree to use effective contraception or be abstinent while on study and for 6 months after the infusion of IMA203 or in line with the instructions provided for investigator's choice treatment (in the control arm)
The patient must have recovered from any side effects of prior therapy to Grade 1 or lower prior to randomization.
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT06743126

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Other Neoplasms Skin

continue...

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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Phase II Study of Intratumoral Administration of L19IL2/L19TNF in Non-melanoma Skin Cancer Patients With Presence of Injectable Lesions

Condition: Carcinoma, Basal Cell/ Carcinoma, Cutaneous Squamous Cell
Primary Completion Date: N/A
Phase: II
Intervention/ Treatment: DRUG: **L19IL2+L19TNF**

Inclusion Criteria:
High-risk, localized (non-metastatic, node negative, single or multifocal) BCC or cSCC amenable to intratumoral injection. / Patients with injectable and measurable regional cutaneous or subcutaneous in-transit or satellite metastasis but without regional nodal involvement are also eligible. / Male or female patients, age 18 - 100 years. / ECOG Performance Status/WHO Performance Status ≤ 1. / Hemoglobin > 10.0 g/dL. / Platelets > 100 x 10^9/L. / ALT and AST, GGT and Lipase ≤ 1.5 x the upper limit of normal (ULN). / Serum creatinine < 1.5 x ULN and GFR > 60 mL/min. / All acute toxic effects (excluding alopecia) of any prior therapy must have resolved to National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE v. 5.0) Grade ≤ 1 unless otherwise specified. / Women of childbearing potential (WOCBP) must have negative pregnancy test results at screening. WOCBP must be using, from screening to three months following the last study drug administration, highly effective contraception methods, as defined by the "Recommendations for contraception and pregnancy testing in clinical trials" issued by the Head of Medicine Agencies' Clinical Trial Facilitation Group and which include, for instance, progesterone-only or combined (estrogen- and progesterone-containing) hormonal contraception associated with inhibition of ovulation, intrauterine devices, intrauterine hormone-releasing systems, bilateral tubal occlusion, vasectomised partner. / Male patients with WOCBP partners must agree to use simultaneously two acceptable methods of contraception (i.e. spermicidal gel plus condom) from the screening to three months following the last study drug administration. / Willingness and ability to comply with the scheduled visits, treatment plan, laboratory tests and other study procedures.
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT04362722

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Uveal Melanoma

continue...

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Currently no study options

continue...

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Brain tumors

continue...

Contact at UCC Hamburg
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Thromboembolism risk after surgery on intracranial tumors with intraoperative application of intermittent pneumatic compression of the legs: A prospective, randomized, single-blinded multicenter study

Condition: Venous thromboembolism during craniotomies
Primary Completion Date: /
Phase: N/A
Intervention/ Treatment: PROCEDURE: **Arm 1: Intraoperative application of intermittent pneumatic venous compression (IPC) of the legs**
Arm 2: No intraoperative application of IPC. The IPC cuffs are applied as in the treatment group, but the air pulse generator is not activated.

Inclusion Criteria:
Elective craniotomy for intracranial pathology
Exclusion Criteria:
Pregnancy / patients incapable of giving consent / Perioperative administration of blood products / Abnormal blood coagulation (platelets and/or plasmatic coagulation, liver disease, use of antiplatelet agents) / Contraindication to the use of IPC (dermatitis in the lower leg area, recent skin grafting; severe arteriosclerosis or other ischemic vascular diseases, massive leg oedema or pulmonary oedema due to heart failure; extreme deformity of the leg) / Pre-existing thromboembolism / Clinical signs of deep vein thrombosis
see Link:

Drks.de:DRKS00034190

Study Test Center	PI / SC	Phone	E-Mail
UKE Neurosurgery	Dr. med. Lasse Dührsen Monique Beyer (SC)	040 7410 52750	l.duehrsen@uke.de m.beyer@uke.de

Thromboembolism risk after surgery on intracranial tumors with intraoperative application of intermittent pneumatic compression of the legs: A prospective, randomized, single-blinded multicenter study

Condition: Progressive Glioblastoma
Primary Completion Date: /
Phase: II
Intervention/ Treatment: DRUG: **Perampanel/ Placebo**

Inclusion Criteria:
Histologically confirmed glioblastoma, progressive or recurrent after 1 or 2 lines of prior treatment, involving one radiotherapy and drug treatments according to institutional standards or prior trial participation, >3 months after end of radiotherapy, and therapy for relapse not yet started. / Cognitive state to understand rationale, necessity and individual consequences of study therapy and procedures.
Female patients with reproductive potentiala must use an approved contraceptive method during and for 4 weeks after the end of trial medication (Pearl Index <1%) / Female patients with reproductive potential: a negative serum pregnancy test (beta- HCG) must be obtained prior to treatment start. / Indication for surgical resection of progressive or recurrent tumour tissue, with a safe waiting interval of up to 5 weeks. / A sufficient amount of resected tumour tissue (minimum 0.5 cm3) is expected to be available for the trial-specific molecular, morphological, functional and perampanel level analysis. / Tumour progression according to RANO criteria / Age ≥18 years / Karnofsky Performance status score (KPS) ≥ 60% / Life expectancy > 3 months / Willing and able to comply with regular neurocognitive and health-related quality of life tests/questionnaires. / Written informed consent

Exclusion Criteria:
Participation in other ongoing interventional clinical trials. / Concomitant intake of enzyme-inducing antiepileptic drugs (EIAEDs: carbamazepine, eslicarbazepine, oxcarbazepine, phenobarbital, phenytoin, primidon, rufinamid) / Steroid intake of more than 4 mg dexamethasone (or equivalence dose) in the last week, or expected indication for it in the foreseeable future / History of other malignancies (except for adequately treated basal or squamous cell carcinoma or carcinoma in situ) within the last 2 years unless the patient has been disease-free for 2 years. / Any clinically significant concomitant disease or condition that could interfere with, or for which the treatment might interfere with, the conduct of the study or the absorption of oral medications or that would, in the opinion of the Principal Investigator, pose an unacceptable risk to the patient in this study. / Any psychological, familial, sociological, or geographical condition potentially hampering compliance with the study protocol requirements and/or follow-up procedures; those conditions should be discussed with the patient before trial entry. / Pregnancy or breastfeeding / History of hypersensitivity to the investigational medicinal product or to any drug with similar chemical structure or to any excipient present in the pharmaceutical form of the investigational medicinal product. / The presence of any other concomitant severe, progressive, or uncontrolled renal, hepatic, haematological, endocrine, pulmonary, cardiac, or psychiatric disease, or signs or symptoms thereof, that may affect the subject’s participation in the study, according to investigators judgement. / Inability to undergo contrast-enhanced MRI. / Inability to undergo surgery (e.g. because of need for continuous anticoagulation, known bleeding disorders, thrombocytopenia <50/nl, pre-existing wound healing problems). / Any continued or planned standard or experimental treatment for the tumour other than resection, including antiangiogenic therapy (such as Bevacizumab), and local therapy in addition to the planned resection, including BCNU wafers, loco-regional hyperthermia, tumour bed irradiation, and photodynamic therapy. / Tumour carries a known mutation in the IDH1 or IDH2 gene / Severe or significant abnormal (≥ Grade 3 CTCAE v5.0) laboratory values for haematology (Hb, WBC, neutrophils, or platelets), liver (serum bilirubin, ALT, or AST) or renal function (serum creatinine). / Known active tuberculosis; HIV infection or active Hepatitis B (HBV) or Hepatitis C (HCV infection, or active infections requiring oral or intravenous antibiotics or that can cause a severe disease and pose a severe danger to lab personnel working on patients’ blood or tissue (e.g. rabies). / Any prior treatment with perampanel / Contraindication against treatment with perampanel
see Link:

euclinicaltrials.eu:2023-503938-52-00

Study Test Center	PI / SC	Phone	E-Mail
UKE Neurosurgery	Prof. Dr. med. Franz Lennard Ricklefs Monique Beyer (SC)	0152 228 179 72	f.ricklefs@uke.de m.beyer@uke.de

Coaching for Coping in Glioblastoma Patients and Caregivers and Its Association With Compliance to TTFields

Condition: Compliance, Patient/ Glioblastoma/ Astrocytoma, Grade IV
Primary Completion Date: 2026-04
Phase: N/A
Intervention/ Treatment: OTHER: **Psychological Intervention**

Inclusion Criteria:
Ability to understand and give an informed consent, capacity to consent / Given informed consent / ≥ 18 years of age / Patients with newly diagnosed glioblastoma / Patients with IDH-mutant Astrocytoma, CNS WHO-Grade 4, newly diagnosed (by biopsy or incomplete tumor resection) / Patients eligible for radiochemotherapy with temozolomide and 60 Gy / Patients before radiochemotherapy phase or within the first 2 weeks / Prescription of TTFields according clinical routine (including but not exclusive to) / Access to a computer and internet / Absence of medical reasons precluding participation in a supportive intervention
Exclusion Criteria:
•Ability to understand and give an informed consent, capacity to consent / Given informed consent / ≥ 18 years of age / Being a family caregiver of a patient with newly diagnosed glioblastoma / Access to a computer and internet / Absence of medical reasons precluding participation in a supportive intervention
see Link:

clinicaltrials.gov/NCT06017063

Study Test Center	PI / SC	Phone	E-Mail
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UKSH Kiel Neurosurgery	Dr. med. Hajrullah Ahmeti Michaela Naeve-Nydahl (SC)	0431 500 23620 0431 500 23675	Hajrullah.Ahmeti@uksh.de Michaela.Naeve-Nydahl@uksh.de

Coaching for Coping in Glioblastoma Patients and Caregivers and Its Association With Compliance to TTFields

Condition: Newly-diagnosed Glioblastoma/ Temporal Lobe
Primary Completion Date: 2028-02-28
Phase: III
Intervention/ Treatment: PROCEDURE: **Anterior temporal lobectomy (ATL)/ Gross Total Resection (GTR)**

Inclusion Criteria:
Suspected glioblastoma with contrast-enhancement in preoperative MRI / Diffuse high-grade glioma in frozen section procedure, newly-diagnosed / Tumor localization (in gadolinium-enhanced MRI): solely temporal, non-dominant side (right hemisphere in right-handed patients, or left-handed patients after testing for dominance): within 6.5 cm from the temporal pole; dominant side (left hemisphere in right-handed patients, all left-handed patients unless additional testing for dominance performed): within 4.0 cm from the temporal pole, as determined dorsally along the Sylvian fissure. / Macroscopic complete resection (no remaining contrast-enhancing tumoral lesion on early postoperative MRI) is achievable (decision of the treating neurosurgeon) / In case further T1-contrast-enhancing and/or T2/FLAIR lesions are detected beyond the resection margins (6.5 cm on the non-dominant side and 4.0 cm on the dominant side), these lesions are not attributed to the tumor (except perifocal edema) but to other conditions according to the local treating neurosurgeon / ≥ 18 and < 75 years of age / KPS ≥ 70% / Estimated life expectancy of at least 6 months / Written informed consent / Cognitive state to understand the rationale and necessity of the study therapy and procedures / Patient compliance and geographic proximity that allow adequate follow-up / For patients with childbearing potential: negative serum pregnancy test (beta-HCG) at baseline visit, patient's commitment to use an approved contraceptive method during the trial and for 3 months after (Pearl index < 1%) / Adequate organ function at baseline visit that does not preclude alkylating chemotherapy and neurosurgical procedures (all criteria required): / Adequate bone marrow reserve: white blood cell (WBC) count ≥ 3.000/µl; granulocyte count > 1.500/µl; platelets ≥ 100.000/µl; haemoglobin ≥ 10 g/dl / Adequate liver function: bilirubin < 1.5 times above upper limit of normal range (ULN); alanine transaminase (ALT/SGPT) and aspartate transaminase (AST/ALAT) < 3 times ULN / Adequate renal function: creatinine < 1.5 times ULN / Adequate blood clotting: Partial Thromboplastin Time (PTT) not exceeding the upper limit of normal range and International Normalized Ratio (INR) <1.5; in case of intake of anticoagulant medication or platelet function inhibitors, the coagulation analysis must show no detectable effect in specific blood tests (as described below) at the time of surgery, and discontinuation of the anticoagulant medication must be justifiable for at least 1 week postoperatively / Direct acting oral anticoagulants (e.g., rivaroxaban, apixaban, edoxaban, dabigatran): anti-Factor Xa (aFXa)-activity within the normal range (rivaroxaban, apixaban, edoxaban), TT/TCT (thrombin clotting time) or ecarin clotting time (ECT) not exceeding the upper limit of normal range (Dabigatran) or verification of subtherapeutic drug levels (apixaban, edoxaban, rivaroxaban, dabigatran) / Vitamin K antagonists (coumarins): INR < 1.5 / Unfractionated heparin (UFH) and argatroban: activated Partial Thromboplastin Time (aPTT) not exceeding the upper limit of normal range / Fractionated heparin/low-molecular-weight heparin (e.g., dalteparin, enoxaparin), heparinoid (e.g., fondaparinux, danaparoid): aFXa-activity within the normal range / Antiplatelet agents (aspirin, clopidogrel, prasugrel, ticagrelor): platelet function analyzer (PFA) test not exceeding the upper limit of normal range (aspirin), whole blood aggregometry not below lower limits of normal range (clopidogrel, prasugrel, ticagrelor)
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT07021339

Study Test Center	PI / SC	Phone	E-Mail
UKE Neurosurgery	Dr. med. Lasse Dührsen Monique Beyer (SC)	040 7410 52750	l.duehrsen@uke.de m.beyer@uke.de

A Multicenter Prospective, Interventional, Randomized Trial of Preoperative Radiosurgery Compared with Postoperative Stereotactic Radiotherapy for Resectable Brain Metastases

Condition: Brain Metastases, Adult
Primary Completion Date:
Phase: N/A
Intervention/ Treatment: RADIATION: **preoperative radiosurgery/ postoperative hypofractionated stereotactic radiotherapy**

Inclusion Criteria:
Provision of signed and dated informed consent form / Stated willingness to comply with all study procedures and availability for the duration of the study / Age ≥18 / Karnofsky performance status ≥60 / Histological diagnosis of a malignant primary or metastatic tumour / Ability to take steroids / No contraindication to magnetic resonance imaging (MRI) / MRI-diagnosis of a clearly demarcated contrast-enhancing brain metastasis up to 4.0 cm diameter indicated for neurosurgical resection (tumorboard decision). Up to 3 other brain metastases suitable for primary radiosurgery/ stereotactic radiotherapy / Survival estimated by primary clinician > 12 months / Platelet count > 100/ml, INR < 1.3, Hb > 7.5 g/dL
Exclusion Criteria:
Radiosensitive histology: germ cell tumour, lymphoma, multiple myeloma / >10 mm midline shift, effacement of the 4th ventricle or other sign of raised intracranial pressure requiring urgent decompressive surgery / More than 4 brain metastases or the diameter of the metastasis for resection >4.0 cm. / More than 1 metastasis requiring resection / Leptomeningeal disease in the CSF or on MRI (unless localized and can be irradiated then resected with the metastasis) / Prior radiation to the brain (SRS/SRT to lesion to be resected and /or WBRT) / Prior resection of a primary or secondary brain tumor / Prior diagnosis of a non-meningioma brain tumor / Prior radionuclide therapy within 30 days / Prior anti-VEGF therapy within 6 weeks / Unable to tolerate radiosurgery immobilization and treatment / Inability to give informed consent / Pregnancy or lactation / Females of reproductive potential not willing to use effective contraception for at least 6 months after radiotherapy / Males of reproductive potential not effective contraception for 3 months after radiotherapy / Lack of likely compliance with protocol and follow-up
see Link:

clinicaltrials.gov/NCT05124236

Study Test Center	PI / SC	Phone	E-Mail
UKSH-Kiel Neurosurgery	PD Dr. Hajrullah Ahmeti Michaela Naeve-Nydahl (SC)	0431 500 23675	Hajrullah.Ahmeti@uksh.de Michaela.Naeve-Nydahl@uksh.de

GIST-tumors

continue...

Contact at UCC Hamburg
Dr. med. Jana Käthe Striefler, Tel. 040/ 7410 53674

Currently no study options

continue...

Side effects of oncological therapies

continue...

Contact at UCC Hamburg
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„Acousia PROHEAR Study Synopsis“

Phase IIa randomized, double-blind, and placebo-controlled multicenter split body trial to determine safety, tolerability, and efficacy of repeated doses of ACOU085 for the prevention of hearing loss in testicular cancer patients receiving cisplatin

Condition: Testicular cancer
Primary Completion Date: /
Phase: II
Intervention/ Treatment: DRUG: **ACOU085/ Placebo**

Inclusion Criteria:
Confirmed diagnosis of testicular cancer with indication for a cis-Pt-containing chemotherapeutic regimen according to current treatment guidelines and site-specific tumor board recommendations / Male adult patients at an age between 18 and 45 years / Planned cis-Pt treatment with a cumulative dose of ≥300 mg/m2 which has to be administered in three chemotherapeutic cycles / Normal or not clinically relevant otoscopic findings in both ears / Normal hearing at both ears according to current WHO criteria for air-conduction 4PTA (0.5/1/2/4 kHz; 0 to 19 dB HL; average of audiometric thresholds at 0.5/1/2/4 kHz) at baseline / Normal hearing at both ears according to ASHA criteria with a hearing threshold at any frequency (0.25 to 12 kHz) not exceeding 20 dB and a 4PTA (0.5/1/2/4 kHz) showing ≤15 dB HL at baseline / Normal distortion product oto-acoustic emissions (DPOAE) present in both ears at baseline / Patient shows normal results at trial start (V1) concerning heart rate (50 to 90 bpm), blood pressure (according to commonly accepted ranges), ECG (no pathological findings), and laboratory parameters (ie, liver and renal function values not clinically significant) / Male patients and their female partner(s) must agree to use 2 forms of contraception (one of which must be a barrier method) during 6 months after trial start (V1) / Patient is cooperative, able to understand all aspects of the trial, and able to speak German comparable to native speakers as per the investigator's discretion / Patient has signed an approved informed consent form indicating that he understands the purpose of and procedures required for the trial, will follow the trial-specific measures, and is willing to participate in the trial

•Exclusion Criteria
•Suspected or diagnosed genetic predisposition to hearing loss (incl. DFNA2 rel. to KCNQ4) / History of middle ear pathology or surgery, otitis externa, chronic otitis media, or recent acute otitis media (within ≤3 months) / History of otologic surgery (excluding myringotomy tubes or simple tympanoplasty) / Meniere‘s disease or secondary endolymphatic hydrops, auto immune hearing loss, inner ear pathology, fluctuating hearing loss, perilymph fistula, cochlear baro-trauma, radiation-induced hearing loss, retro-cochlear lesion, severe tympanosclerosis, atrophic tympanic membrane / Hearing loss of >45 dB averaged at 6 and 8 kHz in either ear / Sudden hearing loss or conductive hearing loss >10 dB at two frequencies in either ear / Asymmetry in hearing thresholds between left and right ear ≥20 dB at any single frequency or ≥10 dB at any 3 consecutive frequencies ≤ 8 kHz / Intake of any ototoxic drugs other than the intended cis-Pt-containing chemotherapeutic drug regimen prior to start of the trial and during the trial period / Previous radiation exposure >35 Gray to complete or parts of the cochlea / Severe concomitant diseases such as heart failure (NYHA II-IV), COPD, bronchial asthma, ongoing malignancies other than testicular cancer, auto-immune or chronic-inflammatory diseases, endocrinological diseases, advanced hepatic or renal failure, and primary complaint of tinnitus • Planned consumption of medications, herbal preparations, and specific food ingredients to treat hearing problems and/or tinnitus during the trial period / Hypersensitivity against any primary or secondary ingredient of IMP/Placebo medication / Male patients with female partners who are pregnant or planning to become pregnant during 6 months after trial start (V1) / Use of any other investigational medicinal product (IMP) within five times the half-life of that IMP/relevant metabolites or one month (whichever is longer) prior to screening and planned use during the trial or up to 30 days after trial completion / Patient has any dependent relationship or employment status with respect to the trial site, the sponsor, the investigator, or any supervisor

•see Link:

dsz-hno.hno.org

Study Test Center	PI / SC	Phone	E-Mail
UKE Head and Neck	Dr. med. Henrike Zech Annette Weber (SC)	040 7410 55458 0152-228 178 00	h.zech@uke.de annette.weber@uke.de
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Randomised controlled study in patients with gastrointestinal tumors on the effect of acupuncture therapy and vibration training against chemotherapy-induced polyneuropathy (CIPN) during oxaliplatin-containing chemotherapy

Condition: Drug-induced polyneuropathy
Primary Completion Date: /
Phase: III
Intervention/ Treatment: OTHER: **Arm 1: Needle acupuncture 1x/week for 20 minutes over 16 weeks/**
Arm 2: Vibration training 2x/week for 16 weeks/ Arm 3: Waiting list for needle acupuncture

Inclusion Criteria:
Gender: All / Minimum age: 18 years / Maximum age: No maximum age
Further Inclusion Criteria: Chemotherapy with an oxaliplatin-containing treatment regimen of at least 3 months duration (cumulative dose of oxaliplatin >500 mg/m2) regardless of intention (adjuvant or palliative) - Minimum age of 18 years
Exclusion Criteria:
Polyneuropathy of other origins (diabetes mellitus, alcohol abuse, paraneoplastic, consequences of previous chemotherapy, hereditary, chronic inflammatory, idiopathic, etc.) chemotherapy, hereditary, chronic inflammatory, idiopathic, etc.) jeopardise the safety of the patients or the feasibility of the study, e.g. coagulopathy or use of anticoagulants with a bleeding time > 3 min, prothrombin time < 40%, platelets < 50. 000/µl or PTT > 50 sec Bacterial infection of the upper or lower extremities near the location of the planned acupuncture therapy Bone fracture of the upper or lower extremities in the last 3 months Osteolysis o Osteosynthesis, knee or hip replacement Acute thrombosis Alcohol dependence Or other diseases which, in the opinion of the investigator, jeopardise the safety of the patients or the feasibility of the study
see Link:

drks.de/DRKS00022970

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Paediatric Oncology & Hematology

http://www.kinderkrebsinfo.de/e1676/e9032/index_ger.html

Studienverbund Pädiatrische Hämatologie und Onkologie Nordwest – Gemeinsam für eine bessere Medizin. (studienverbund-nordwest.de)

continue...

Contact at UCC Hamburg
Prof. Dr. med. Kai Witetchek, Tel. 040/ 7410 56822

Cross-entity studies (Basket studies)

continue...

Contact at UCC Hamburg
PD Dr. med. Andreas Block, MBA, 040/ 7410-56305
Dr. med. Winfried Alsdorf, 040 0152 22817664

A Phase 1/2, Open Label, Dose-escalation, and Dose-expansion Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Efficacy of D3S 001 Monotherapy or Combination Therapy in Subjects With Advanced Solid Tumors With a KRAS p.G12C Mutation

Condition: KRAS P.G12C
Primary Completion Date: 2027-02
Phase: I/II
Intervention/ Treatment: DRUG: **D3S-001/ Pembrolizumab/ Cisplatin/ Carboplatin/ Pemetrexed/ Cetuximab**

Inclusion Criteria:
Subject must have a histologically or cytologically confirmed metastatic or locally advanced solid tumor which is progressing. / Subject must have documented KRAS p.G12C mutation identified within the last 5 years by a local test on tumor tissue or blood. / Subject must have measurable disease per RECIST v1.1. / Subject must have Eastern Cooperative Oncology Group (ECOG) perform. status of 0 or 1. / •Subject must have adequate organ and marrow function within the screening period.

Exclusion Criteria:
Subject has any prior treatment with other treatments without adequate washout periods as defined in the protocol. / Subject has uncontrolled intercurrent illness, including but not limited to, ongoing or active infection, uncontrolled or significant cardiovascular disease, serious chronic gastrointestinal conditions associated with diarrhea, or psychiatric illness/social situations that would limit compliance with study requirements, substantially increase risk of incurring AEs, or compromise the ability of the subject to give written informed consent. / Subject has unresolved treatment-related toxicities from previous anticancer therapy of NCI CTCAE Grade ≥2 (with exception of vitiligo or alopecia). / Subject has active gastrointestinal disease or other that could interfere significantly with the absorption, distribution, metabolism, or excretion of oral therapy. / Concurrent participation in any clinical research study involving treatment with any investigational drug, radiotherapy, or surgery, except for the nontreatment phases of these studies (e.g., follow-up phase).
see Link:

clinicaltrials.gov/NCT05410145

Study Test Center	PI / SC	Phone	E-Mail
Hämatolisch-Onkologische Praxis Eppendorf	Prof. Dr. med. Alexander Stein Dr. med. Eray Gökkurt	040-360352222	stein@hope-hamburg.de goekkurt@hope-hamburg.de

Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Phase Ia/Ib First-In-Human Clinical Trial to Evaluate the Safety, Tolerability and Initial Anti-Tumor Activity of IMA401, a Bispecific T Cell Engaging Receptor Molecule (TCER®), as Monotherapy or in Combination With Checkpoint Inhibitor in Patients With Recurrent and/or Refractory Solid Tumors.

Condition: Refractory Cancer/ Recurrent Cancer/ Solid Tumor, Adult/ Cancer
Primary Completion Date: 2025-11
Phase: I
Intervention/ Treatment: BIOLOGICA: **IMA401 (Phase Ia)/ Pembrolizumab (Phase Ia)/ IMA 401 (Phase Ib)**

Inclusion Criteria:
Patients must have voluntarily signed a written ICF, be able to understand and comply with clinical trial procedures / Patients ≥ 18 years old / Patients must have pathologically confirmed and documented advanced and/or metastatic NSCLC or HNSCC, other solid tumor may be considered / Confirmed HLA status and IMA401 tumor target MAGE-A4 and/or MAGE-A8 expression / Life expectancy > 2 months / ECOG Performance Status of 0 to 1 / Measurable disease according to RECIST 1.1 / Adequate baseline hematologic, renal and hepatic function; acceptable coagulation status / Patients must have recurrent and/or refractory solid tumors and must have received or not be eligible for all available indicated standard of care treatments / The patient must have recovered from any side effects of prior therapy to Grade 1 or lower (except for non-clinically significant toxicities; e.g., alopecia, vitiligo) prior to treatment start. As determined by the investigator, the patient may still be eligible if the patient has not fully recovered from Grade ≥ 2 toxicities, in case if these toxicities are not anticipated to further improve (e.g., chronic peripheral neuropathy) and such toxicities are not anticipated to worsen with the IMA401 therapy

Exclusion Criteria:
Other active malignancies that require treatment or that might interfere with the trial endpoints (ongoing adjuvant anti-hormonal treatment is allowed) / History of hypersensitivity to components of IMA401, CPI treatment or rescue medications, contraindication for pembrolizumab / Patients with prior allogeneic stem cell transplantation or organ transplantation / Patients with autoimmune diseases needing disease-directed treatment / Any serious or uncontrolled health condition, which, in the opinion of the Investigator, would place the subject at undue risk from the study, impair the ability of the subject to receive protocol specified therapy, or interfere with the interpretation of study results / Positive for HIV or with active hepatitis B or C infection. / Patients with active infection / Systemic corticosteroids (≥ 10 mg/day prednisone or equivalent) received 2 weeks prior to starting trial treatment / Patients with active central nervous system metastases and leptomeningeal metastases
see Link:

clinicaltrials.gov/NCT05359445

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Phase I Study to Evaluate Safety and Early Signs of Efficacy of the Human Monoclonal Antibody-cytokine Fusion Protein IL12-L19L19.

Condition: Advanced Solid Tumor/ Metastatic Solid Tumor
Primary Completion Date: 2025-12
Phase: I
Intervention/ Treatment: DRUG: **IL12-L19L19**

Inclusion Criteria:
Male or Female aged 18 to 80 years at the time of consent. / Patients must have a histological or cytological diagnosis of advanced/metastatic immunotherapy responsive solid carcinoma for which immune checkpoint blockade is approved, that has progressed on immune checkpoint-blockade therapy. / Patients must have received an immune checkpoint blockade therapy-based regimen as prior treatment. / Only patients without other therapeutic alternatives with curative or survival prolonging potential per investigator judgement are able to participate. / Subjects must have had clinical benefit in terms of disease control (CR/PR/SD) while on checkpoint inhibitor treatment defined as ≥ 3 month free from progression from initial imaging documenting advanced/metastatic disease followed by radiographic disease progression after checkpoint inhibitor per investigator's opinion. / Patients must have progressive disease or relapse at the time of screening. / Patients may have previously received chemotherapy, immunotherapy or radiation therapy. Such therapies must be completed at least 4 weeks prior to study drug administration. Radiotherapy within 4 weeks of the first dose of study drug, is allowed for palliative radiotherapy to a limited field, such as for the treatment of bone pain or a focally painful tumor mass. During the expansion part, to allow evaluation of response to treatment, patients must have remaining measurable disease that has not been irradiated. / Eastern cooperative oncology group (ECOG) performance status ≤ 2. / Patient has an estimated life expectancy of at least 12 weeks. / At least one unidimensionally measurable lesion either by computed tomography (CT), MRI or PET/CT as defined by RECIST (v. 1.1) for solid tumors. / Documented negative test for HIV-HBV-HCV. For HBV serology: the determination of HBsAg, and anti-HBcAg-Ab is required. In patients with serology documenting previous exposure to HBV (i.e., anti-HBs Ab with no history of vaccination and/or anti-HBc Ab), negative serum HBV-DNA is required. For HCV: HCV-RNA or HCV antibody test. Subjects with a positive test for HCV antibody but no detection of HCV-RNA indicating no current infection are eligible. / All acute toxic effects (excluding alopecia and fatigue) of any prior therapy (including surgery, radiation therapy, chemotherapy) must have resolved to National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) (v. 5.0) Grade ≤ 1. / Full resolution of checkpoint blockade therapy-related adverse effects (including immune-related adverse effects) and no treatment for these AEs for at least 4 weeks prior to the time of enrollment. The only exception are patients with checkpoint blockade induced hypothyroidism and hypophysitis if these patients are on stable maintenance therapy with on levothyroxine or steroids (≤ 10 mg prednisone equivalent) for at least 2 months prior dosing. / No history of severe immune related adverse effects from prior given immune checkpoint blockade therapy (CTCAE Grade 4; CTCAE Grade 3 requiring treatment >4 weeks). / Female patients: negative blood pregnancy test at Screening for women of childbearing potential (WOCBP)*. WOCBP must agree to use, from the screening to six months following the last study drug administration, highly effective contraception methods, as defined by the "Recommendations for contraception and pregnancy testing in clinical trials" issued by the Head of Medicine Agencies' Clinical Trial Facilitation Group (www.hma.eu/ctfg.html) and which include, for instance, progesterone-only or combined (estrogen- and progesterone-containing) hormonal contraception associated with inhibition of ovulation, intrauterine devices, intrauterine hormone-releasing systems, bilateral tubal occlusion or vasectomized partner. / Male patients: male subjects able to father children must agree to use two acceptable methods of contraception throughout the study (e.g. condom with spermicidal gel). Double-barrier contraception is required. 1.Negative TB test (e.g. Mantoux or Quantiferon assay). / A personally signed and dated informed consent document indicating that the subject has been informed of all pertinent aspects of the study and has given consent to participate in the study. / Willingness and ability to comply with the scheduled visits, treatment plan, laboratory tests and other study procedures. / Women of childbearing potential are defined as females who have experienced menarche, are not postmenopausal (12 months with no menses without an alternative medical cause) and are not permanently sterilized (e.g., tubal occlusion, hysterectomy, bilateral oophorectomy or bilateral salpingectomy) / Informed consent must be obtained for all the patients prior to any screening procedure for the present study.
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT04471987

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Effectiveness of a short-term high-fiber dietary intervention in patients with adenocarcinoma of the lung, esophagus, or stomach undergoing planned immunochemotherapy

Condition: Patients with bronchial and esophageal/gastric carcinomas and indication for immunotherapy
Primary Completion Date: N/A
Phase: N/A
Intervention/ Treatment: 60 patients with histologically confirmed EGA or lung adenocarcinoma with an indication for immunotherapy.

Inclusion Criteria:
Gender: All / Minimum age: 18 years / No maximum age / **Additional inclusion criteria:** Histologically confirmed EGA or lung adenocarcinoma with indication for immunotherapy or immunochemotherapy / The participant gives his/her written consent to participate in the study / The participant is at least 18 years of age on the date of signing the consent form / No prior systemic anticancer therapy for metastatic disease (e.g., cytotoxic or targeted agents). / ECOG (Eastern Cooperative Oncology Group) performance status score of ≤ 2
Exclusion Criteria:
Major surgery within 2 weeks of the start of the study intervention or patients who have not fully recovered from the effects of previous surgery / Risk of malnutrition: weight loss of more than 10% of body weight in the last 6 weeks, NRS score ≥ 3, BMI < 18.5, albumin level < 20 mg/dl, or if 50% of daily energy is provided by enteral/parenteral nutrition / Short bowel syndrome, enterostomy / Previous intestinal obstruction or risk of intestinal obstruction / Participants with diagnosed immunodeficiency or those receiving chronic systemic steroid therapy (at a dosage of more than 10 mg daily prednisone equivalent) or any other form of immunosuppressive therapy within 7 days prior to the first dose of study medication. / Participants with an active infection requiring systemic therapy. / Participants with a known history of infection with human immunodeficiency virus (HIV) or hepatitis..
see Link:

Drks.de: DRKS00036482

Study Test Center	PI / SC	Phone	E-Mail
UKE UCC Hamburg	PD Dr. med. Marianne Sinn Julia von Grundherr (SC)	040-7410-56882 040-7410-51845	ma.sinn@uke.de j.von-grundherr@uke.de

Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

23 „GOBLET“, REO 029, AIO-KRK-0320ass

A phase 1 / 2 multiple-indication biomarker, safety, and efficacy study in advanced or metastatic Gastrointestinal cancers exploring treatment combinations with Pelareorep and Atezolizumab

Condition: **Cohort 1**: First-line locally advanced/metastatic unresectable pancreatic ductal adenocarcinoma (PDAC) / **Cohort 2**: First-line mCRC, MSI-H or dMMR / **Cohort 3**: Third-line mCRC, independent of MSI/dMMR status / **Cohort 4:** Second-line (or higher) locally advanced/metastatic unresectable squamous cell carcinoma of the anal canal (SCCA) after prior systemic chemotherapy

Primary Completion Date: /

Phase: I/II

Intervention/ Treatment: Pelareorep and atezolizumab added to SOC gemcitabine and nab paclitaxel / Cohort 2: pelareorep and atezolizumab Cohort 3: pelareorep and atezolizumab added to SOC trifluridine/tipiracil Cohort 4: pelareorep and atezolizumab

Inclusion Criteria:

Cohort 1: Locally Advanced/Metastatic Unresectable Pancreatic Ductal Adenocarcinoma 1L Patients with histologically or cytologically confirmed locally advanced/metastatic unresectable PDAC who are eligible for 1L SOC chemotherapy with gemcitabine plus nab-paclitaxel. / **Cohort 2**: Metastatic Colorectal cancer 1L (MSI-H/dMMR) Patients with histologically or cytologically confirmed metastatic colorectal adenocarcinoma (mCRC) with MSI-H/dMMR tumors and no prior systemic treatment for metastatic disease. / **Cohort 3**: Metastatic Colorectal cancer 3L Patients with histologically or cytologically confirmed mCRC, independent of MSI/dMMR status, who failed (and/or did not tolerate) 2 prior lines of treatment, including oxaliplatin, irinotecan, 5-FU, ± targeted agents such as bevacizumab and/or an anti-epidermal growth factor receptor (EGFR) antibody who are eligible for 3L SOC chemotherapy with trifluridine/tipiracil. (See Appendix 6 for guidance on determining eligibility for this cohort). / **Cohort 4**: Locally Advanced/Metastatic Unresectable Anal cancer ≥2L Patients with histologically or cytologically confirmed locally advanced/metastatic unresectable SCCA of viral (HPV) or non-viral origin who failed (and/or did not tolerate) prior systemic chemotherapy. / **All Cohorts:** Patients must: 1. Provide written informed consent prior to study participation. / 2. Be at least 18 years of age on the day of providing consent. / 3. Have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 within 7 days of start of treatment. / 4. Have measurable lesions per RECIST v1.1 / 5. Have adequate organ function at the time of enrollment as defined by: • Absolute neutrophil count ≥1200/mm3 • Platelet count ≥7.5 × 104/mm3 • Hemoglobin >8 g/dL (blood transfusion >2 weeks before testing is permitted) • Aspartate aminotransferase (AST), alanine aminotransferase (ALT) ≤2.5 x the upper limit of normal (ULN; ≤5 x ULN in patients with liver metastasis) • Total bilirubin ≤1.5 x ULN • Creatinine ≤1.5 x ULN • Lipase ≤1.5 x ULN • International normalized ratio (INR) ≤1.5 x ULN and partial thromboplastin time (PTT) or activated partial thromboplastin time (aPTT) ≤1.5 x ULN unless receiving treatment with therapeutic anticoagulation. Patients being treated with anticoagulant, e.g., heparin, will be allowed to participate provided no prior evidence of an underlying abnormality in these parameters exists. Close monitoring per local SOC will be performed until INR and PTT are stable based on a pre-dose measurement as defined by the local SOC. / 6. Have recovered to ≤grade 1 or baseline for all adverse events (AEs) due to previous therapies or surgeries. For female patients of childbearing potential and male patients with partners of childbearing potential, agreement (by patient and/or partner) to use a highly effective form(s) of contraception (i.e., one that results in a low failure rate (<1% per year) when used consistently and correctly) and to continue its use for 6 months after the last dose of study drug.

see Link:

aio-portal.de

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG

Universitätsklinikum Hamburg-Eppendorf

An Open Label, Phase 1, Treatment Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of IDE397 (MAT2A Inhibitor) In Adult Participants With Advanced Solid Tumors

Condition: Solid Tumor
Primary Completion Date: 2026-12-31
Phase: I
Intervention/ Treatment: DRUG: **IDE397/ Docetaxel/ Paclitaxel/ Sacituzumab govitecan**

Inclusion Criteria:
Participant must be at least 18 years of age / Advanced or metastatic solid tumor that has progressed on at least one prior line of treatment or is intolerant to additional effective standard therapy / Have evidence of homozygous loss of MTAP or MTAP deletion / Willing to undergo paired fresh biopsy (pre- and post-treatment) procedure. Exceptions may be made for feasibility and safety concerns / Measurable disease / ECOG performance status <= 1 / Adequate organ function / Able to swallow and retain orally administered study treatment / Recovery from acute effects of prior therapy / Able to comply with contraceptive/barrier requirements

Exclusion Criteria:
Known symptomatic brain metastases / Known primary CNS malignancy / Current active liver or biliary disease / Impairment of gastrointestinal (GI) function / Active uncontrolled infection / Clinically significant cardiac abnormalities / Previous treatment with a MAT2A inhibitor and / or PRMT inhibitor or sacituzumab govitecan / Systemic anti-cancer therapy or major surgery within 4 weeks prior to study entry / Radiation therapy within 2 weeks prior to study entry / Prior irradiation to >25% of the bone marrow / Current use or anticipated need for food or drugs that are known strong CYP3A4/5 inhibitors or inducers / Currently receiving another investigational study drug. / Known or suspected hypersensitivity to IDE397/excipients or components

see Link:

clinicaltrials.gov/NCT04794699

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

23 „Cancer Survivors 60+“

The Cancer Survivors 60+ project focuses on supplementing and expanding UCCH's existing care services and portfolio on the topic of “Life after cancer” (with a current focus on exercise and nutrition therapy as well as young adults) for the over-60 age group, which has so far been insufficiently covered in research projects and care throughout Germany.The main objective is to develop and implement a structured cancer aftercare program, including a model consultation at the UCCH, which addresses the special needs of the 60+ target group with a focus on cardiovascular risk factors and a healthy lifestyle.Translated with DeepL.com (free version)

Condition: Cancer Survivors
Estimated:Completion Date: /
Phase: N/A
Intervention/ Treatment: BEHAVIORAL: **Medical follow-up consultation with preparation of an individual aftercare plan- Consultations on exercise and nutrition (45-60 min each) by specialized therapists-Topic-specific information events (online every 8 to 12 weeks)**

Inclusion Criteria:
Patients who have completed tumor therapy and are currently undergoing cancer aftercare / Completion of tumor therapy ≤ 5 years / Age ≥ 60 years
Exclusion Criteria:
Palliative patients or patients with advanced cancer / Patients currently undergoing cancer therapy (except: long-term maintenance therapy such as adjuvant hormone therapy)
see Link:

DRKS.de/DRKS00034429

Study Test Center	PI / SC	Phone	E-Mail
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23 „ORPHYS“

Life-threatening physical illness may powerfully re-activate existential conflict. There is little evidence to date on the effectiveness of relationship-focused therapies in this patient group.The aim of this study is to pilot a psychodynamic treatment for patients with advanced cancer and high psychological distress.

Condition: Malignant Neoplasms/ Carcinoma, Palliative Care
Estimated Completion Date: 2025-06-30
Phase: N/A
Intervention/ Treatment: BEHAVIORAL: **Short-term psychodynamic psychotherapy for patients with serious physical illness**

Inclusion Criteria:
18 years and older / UICC stage IV solid tumor / Informed consent / Current physical condition that allows for at least 12 therapy sessions / Indication: Presence of a mental disorder with existential stress and limitations in coping capacity
Exclusion Criteria:
Acute suicidality / Psychotic disorder (ICD-10: F2 diagnosis) / Substance dependence or abuse (ICD-10: F1 diagnosis) / Structural deficits that interfere with attending to regular appointments / Other psychotherapeutic treatment / Severe cognitive impairment / Severe physical impairment / Insufficient German to give informed consent and complete self-report questionnaires
see Link:

clinicaltrials.gov/NCT05520281

Study Test Center	PI / SC	Phone	E-Mail
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Cellular therapies

continue...

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Dr. med. Winfried Alsdorf, Tel.: 01522-281 7664

Phase I/IIa, First-in-human (FIH), Open-label, Dose Escalation Trial With Expansion Cohorts to Evaluate Safety and Preliminary Efficacy of CLDN6 CAR-T With or Without CLDN6 RNA-LPX in Patients With CLDN6-positive Relapsed or Refractory Advanced Solid Tumors

Condition: Solid Tumor
Primary Completion Date: 2027-01
Phase: I/II
Intervention/ Treatment: BIOLOGICAL: **CLDN6 CAR-T/ CLDN6 uRNA-LPX/CLDN6 modRNA-LPX**

Inclusion Criteria:
Each patient enrolled in the trial must have CLDN6-positive tumor regardless of tumor histology defined as ≥ 50% of tumor cells expressing ≥ 2+ CLDN6 protein using a semi-quantitative immunohistochemistry (IHC) assay in a central laboratory for specific detection of CLDN6 protein expression in formalin-fixed, paraffin-embedded (FFPE) neoplastic tissues. /
Availability of a FFPE tumor tissue sample. FFPE can be from an archival tumor tissue sample, and it should be from the most recent tumor tissue obtained. If this is not available, patient must be biopsied for CLDN6 staining. / Must have histological documentation of the original primary tumor via a pathology report. / Must have measurable disease per RECIST 1.1 (except for germ cell tumors, where patients can be evaluated according to cancer-Antigen (CA)-125, Alpha-fetoprotein or human chorionic gonadotropin [as applicable] or ovarian cancer, where patients can be evaluated according to CA-125. The pre-treatment sample must be at least twice the upper limit of normal). / Must have a histologically confirmed solid tumor that is metastatic or unresectable and for which there is no available standard therapy likely to confer clinical benefit, or patient who is not a candidate for such available therapy. / Must be ≥ 18 years of age at the time the pre-screening informed consent is signed. /
Must sign an informed consent form (ICF) indicating that he or she understands the purpose of and procedures required for the trial and are willing to participate in the trial prior to any trial-related assessments or procedures. / Must have an Eastern Cooperative Oncology Group performance status of 0 to 1. / Must have adequate coagulation function at screening as defined in the protocol. / Must have adequate hematologic function at screening as defined in the protocol. / Must have adequate hepatic function at screening as defined in the protocol. / Must have adequate renal function at screening as defined in the protocol. / Must be able to attend trial visits as required by the protocol. / Women of childbearing potential (WOCBP) must have a negative serum (beta-human chorionic gonadotropin) test/value at screening. Patients who are post-menopausal or permanently sterilized can be considered as not having reproductive potential. / WOCBP must agree not to donate eggs (ova, oocytes) for the purposes of assisted reproduction during the entire trial and thereafter. / WOCBP and men that are sexually active with a WOCBP and have not had a vasectomy must agree to use highly effective birth control method(s), as defined in the protocol. True abstinence is an acceptable alternative to the use of contraception. / Men must agree not to father a child or donate sperm, and WOCBP must agree not to become pregnant during the trial and for at least 12 months after the CLDN6 CAR-T infusion or CLDN6 RNA-LPX treatment. / **For Part 2 only:** Histologically or cytologically confirmed solid tumor fulfilling inclusion criteria 1-4 that is metastatic or unresectable, and for whom there is no available standard therapy likely to confer clinical benefit, or patient who is not a candidate for such available therapy.
see Link:

clinicaltrials.gov/NCT04503278

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG

Universitätsklinikum Hamburg-Eppendorf

Phase 1 Study Evaluating Genetically Modified Autologous T Cells Expressing a TCR Recognizing a cancer/Germline Antigen as Monotherapy or in Combination With Nivolumab in Patients With Recurrent and/or Refractory Solid Tumors

Condition: Refractory cancer/ Recurrent cancer/ Solid Tumor, Adult/ cancer
Primary Completion Date: 2028-12
Phase: I
Intervention/ Treatment: DRUG: **Nivolumab (Opdivo®)**_BIOLOGICAL: **IMA203 Product/ IMA203 product- flat dose/ IMA203CD8 Product_** DEVICE: **IMADetect®**

Inclusion Criteria:
Patients must have recurrent/progressing and/or refractory solid tumors and must have received or not be eligible for all available indicated SoC treatment.
Eastern Cooperative Oncology Group (ECOG) performance status 0-1 / HLA phenotype positive for the study / Measurable disease according to RECIST 1.1 / Adequate selected organ function per protocol / Patient's tumor must express tumor antigen by "IMADetect® RT-qPCR / Life expectancy more than 5 months / Female patient of childbearing potential must use adequate contraception prior to study entry until 12 months after the infusion of IMA203/IMA203CD8 / Male patient must agree to use effective contraception or be abstinent while on study and for 6 months after the infusion of IMA203/IMA203CD8 The patient must have recovered from any side effects of prior therapy to Grade 1 or lower prior to lymphodepletion.

Exclusion Criteria:
History of other malignancies (except for adequately treated basal or squamous cell carcinoma or carcinoma in situ) within the last 3 years / Pregnant or breastfeeding / Serious autoimmune disease Note: At the discretion of the investigator, these patients may be included if their disease is well controlled without the use of immunosuppressive agents. / History of cardiac conditions as per protocol / Prior stem cell transplantation or solid organ transplantation / Concurrent severe and/or uncontrolled medical disease that could compromise participation in the study / History of or current immunodeficiency disease or prior treatment compromising immune function at the discretion of the treating physician / Positive for HIV infection or with active hepatitis B virus (HBV) or active hepatitis C virus (HCV) infection. Patients with LDH greater than 2.0-fold ULN. / Any condition contraindicating leukapheresis, lymphodepletion, low-dose IL-2, and/or IMA203/IMA203CD8 treatment / Patients with active brain metastases / Concurrent treatment in another clinical trial. / For nivolumab treatment, patients must not have a history of severe immune-related toxicities, defined as any Grade 3 or 4 toxicities related to prior PD1/PD-L1 inhibitor therapy (e.g., atezolizumab, pembrolizumab or nivolumab etc.). / Other protocol defined inclusion/exclusion criteria could apply
see Link:

clinicaltrials.gov/NCT03689124

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Leukemias

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Acute lymphoblastic leukemia (ALL)

continue...

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25a „GMALL-EVOLVE“

A Multicentre, Randomized Trial in Adults With de Novo Philadelphia-Chromosome Positive Acute Lymphoblastic Leukemia to Assess the Efficacy of Ponatinib Versus Imatinib in Combination With Low-intensity Chemotherapy, to Compare End of Therapy With Indication for SCT Versus TKI, Blinatumomab and Chemotherapy in Optimal Responders and to Evaluate Blinatumomab in Suboptimal Responders

Condition: Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia
Primary Completion Date: 2029-07-01
Phase: II
Intervention/ Treatment: DRUG: **Imatinib/ Ponatinib/ Blinatumomab**_OTHER: **Indication for stem cell transplantation**

Inclusion Criteria:
Male or female patients >= 18 years, <=65 years / Philadelphia chromosome or BCR-ABL1 positive ALL / Not previously treated except with corticosteroids ≤ 7 days, standard GMALL prephase with dexamethasone and cyclophosphamide including intrathecal therapy, hydroxyurea, a single dose vincristine or other cytostatic drugs and start of standard induction for Ph-positive ALL (1 dose vincristine, 1 dose of Rituximab, 2 doses dexamethasone and up to 5 days Imatinib) / ECOG performance status ≤2 / Signed written inform consent / Molecular evaluation for BCR-ABL1 performed /
Negative pregnancy test in women of childbearing potential / Woman of childbearing potential willing to use 2 highly effective methods of contraception while receiving study treatment and for an additional 3 months after the last dose of study treatment (Pearl-Index <1%). Male who has a female partner of childbearing potential willing to use 2 highly effective forms of contraception while receiving study treatment and for at least an additional 3 months after the last dose of study treatment (Pearl-Index <1%). /
Normal serum levels > LLN (lower limit of normal) of potassium and magnesium, or corrected to within normal limits with supplements, prior to the first dose of study medication / Serum lipase ≤ 1.5 x ULN. For serum lipase > ULN - ≤ 1.5 x ULN, value must be considered not clinically significant and not associated with risk factors for acute pancreatitis / Normal QTcF interval ≤450 ms for males and ≤470 ms for females / Signed and dated written informed consent is available / Participation in the registry of the German Multicenter Study Group for Adult ALL (GMALL)
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT06061094

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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Phase 1/2 Study to Evaluate the Safety and Efficacy of AZD0486 in Adolescent and Adult Participants With Relapsed or Refractory B-Cell Acute Lymphoblastic Leukaemia

Condition: B-cell Acute Lymphoblastic Leukemia (B-ALL)
Primary Completion Date: 2026-06-30
Phase: I/II
Intervention/ Treatment: DRUG: **AZD0486**

Inclusion Criteria:
Age: 16 years and older (Part A), 12 years and older (Parts B and C). / Participants with B-cell Acute Lymphoblastic Leukemia with CD19 expression by local lab with: Bone marrow infiltration with >/= 5% blasts / Either relapsed or refractory after a minimum of 2 prior therapies or after 1 prior line of therapy if no SOC available option. / Philadelphia positive participants are allowed in Part A if intolerant or refractory to TKIs. / For participants older than 16 years, Eastern Cooperative Oncology Group (ECOG) Performance Status less than or equal to 2. For Participants 16 years or younger, Lansky score more or equal to 50%. / The above is a summary, other inclusion criteria details may apply.

Exclusion Criteria:
Active CNS involvement by B-ALL, defined by presence of ALL blasts in CSF (CNS2 and CNS3 criteria). / Isolated extramedullary disease relapse. / Testicular leukemia / History or presence of clinically relevant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis; or prior Grade 4 neurotoxicity with CAR-T or TCE therapy. / History of other malignancy (with certain exceptions). / Unresolved AEs >/= Grade 2, from prior therapies / Prior therapy with TCEs within 4 weeks, CAR T-cell therapy or autologous HSCT within 8 weeks or prior alloSCT within 12 weeks of start of therapy. / GVHD requiring immunosuppressive therapy within 3 weeks prior to AZD0486 treatment. / The above is a summary, other exclusion criteria details may apply.

see Link:

clinicaltrials.gov/NCT06137118

Study Test Center	PI / SC	Phone	E-Mail
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25a „GMALL-Isatuximab“

A multicenter, single-arm phase II study to assess the safety, tolerability, and efficacy of Isatuximab in adult patients with cytologic or molecular relapsed/refractory CD38 positive T-cell acute lymphoblastic leukemia

Condition: Acute Lymphoblastic Leukemia
Primary Completion Date: 31.12.2025
Phase: II
Intervention/ Treatment: DRUG: **Emavusertib/ Azacitidine/ Venetoclax**

Inclusion Criteria:
Patients with CD38 positive T-ALL fitting either to the definitions for cohort 1 or cohort 2: /
Cohort 1: In relapse or with primary refractory disease defined as ≥5% blasts in bone marrow after at least three chemotherapy cycles (induction I-II, consolidation I) with the following additional / **specifications:**early relapse within 12 months from first achievement of CR **or** / late relapse later than 12 months from first achievement of CR or / primary refractory disease without any CR or / any relapse after stem cell transplantation orany refractory relapse, defined as no response to at least one salvage therapy or / any second or later relapse and / Availability of patient material with blast cells (bone marrow or peripheral blood) for central MRD assessment. /
Cohort 2: In complete hematological remission (defined as less than 5% blasts in bone marrow and no evidence of extramedullary disease) after at least three chemotherapy cycles (induction I-II, consolidation I) / Detection of quantifiable MRD at a level of ≥10-4, either as molecular failure without prior achievement of molecular remission or molecular relapse after prior achievement of molecular remission / MRD assay at the central reference lab with at least one marker a minimum sensitivity of 10-4 / MRD detection for study inclusion after an interval of at least 2 weeks from last systemic chemotherapy including antibody therapy (in patients without clonal molecular MRD marker, MRD testing can be based on flow-cytometry established in reference laboratory) / ECOG status: Cohort 1: 0-2 Cohort 2: 0-1 / Age 18 years / Evidence of a personally signed and dated informed consent indication that the patient has been informed of all pertinent aspects of the study / Patient must be willing and able **to comply with scheduled visits, treatment plan, laboratory tests and other study procedures / Regeneration from last chemotherapy defined as follows:**
Cohort 1: - Platelets □10.000/µL (platelet transfusion allowed) / - Hemoglobin □ 7.5 g/dL (red blood cell transfusion allowed) /
Cohort 2: - Neutrophils □1.000/µL / - Platelets □50.000/µL / - Hemoglobin □9 g/dL / Adequate liver function defined as follows: Study Protocol GMALL-Isatuximab / - Bilirubin ≤ 1.5 ULN (unless Gilbert Meulengracht disease or classified as result of liver infiltration by investigator) / - AST and ALT ≤ 2.5 x ULN (unless classified as result of liver infiltration by investigator) / Adequate renal function defined as follows: / - Serum creatinine ≤ 2 x ULN / - Any serum creatinine level associated with a calculated creatinine clearance □ 40 mL/min / Negative pregnancy test in women of childbearing potential (WOCBP)
WOCBP must commit to either abstain continuously from heterosexual sexual intercourse or to use 2 / methods of reliable birth control simultaneously (for details see 11.2). / Men who are sexually active with a WOCBP must agree to use a barrier method of contraception (for details see 11.2). / Participation in the registry of the German Multicenter Study Group for Adult ALL (GMALL)
Exclusion Criteria:
see Link:

Euclinicaltrials.eu:2023-507899-47-00

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AML & MDS

continue...

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MidOStaurin + Gemtuzumab OzogAmIcin Combination in First-line Standard Therapy for Acute Myeloid Leukemia (MOSAIC)

Condition: Acute Myeloid Leukemia
Primary Completion Date: 2027-04
Phase: I/II
Intervention/ Treatment: DRUG: **MODULE: conventional chemotherapy (Cytarabine+Daunorubicin) in combination with midostaurin+GO/ MAGNOLIA-trial: Midostaurin associated with conventional chemotherapy (AraC+DNR)+GO/ MAGNOLIA-trial: conventional chemotherapy (AraC+DNR)+GO/ MAGMA-trial:GO associated with conventional chemotherapy (AraC+DNR)+Midostaurin/ MAGMA-trial: conventional chemotherapy (AraC+DNR)+Midostaurin**

Inclusion Criteria:
Written informed consent / Newly diagnosed AML according to the criteria of the World Health Organisation plus the following molecular or cytogenetic specifications: / Phase I Trial - MODULE: t(8;21)/RUNX1-RUNX1T1 or inv(16) or t(16;16)/CBFB-MYH11 or / FLT3-ITD or FLT3-tyrosine kinase domain (FLT3-TKD) / Phase II Trial – MAGNOLIA t(8;21)/RUNX1-RUNX1T1 or inv(16) or t(16;16)/CBFB-MYH11 / Phase II Trial – MAGMA FLT3-ITD or FLT3-TKD / Absence of mutations in CBF genes (i.e. t(8;21)/RUNX1-RUNX1T1 or inv(16) or t(16;16)/CBFB-MYH11) / Male and female patients aged 18 - ≤ 75 years in Phase I Trial – MODULE, MAGMA and MAGNOLIA / Eastern Cooperative Oncology Group (ECOG) Score of 0-2 / Life expectancy > 14 days / Adequate hepatic and renal function / alanine aminotransferase / aspartate transaminase ≤ 2.5 x ULN / Bilirubin < 2 x upper limits of normal / Creatinine < 1.5 x upper limits of normal or Creatinine clearance > 40 ml/min / White blood cell count < 30 × 10^9/L. Note: Hydroxyurea and/or a dose of 100-200 mg/m^2 cytarabine per day for up to 3 days (for emergency use for clinical stabilization) is permitted to meet this criterion.
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT04385290

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Venetoclax Plus Azacitidine Versus Standard Intensive Chemotherapy for Patients With Newly Diagnosed Acute Myeloid Leukemia (AML) and NPM1 Mutations Eligible for Intensive Treatment

Condition: Acute Myeloid Leukemia
Primary Completion Date: 2028-09
Phase: II
Intervention/ Treatment: DRUG: **Venetoclax plus Azacitidine/ standard of care chemotherapy plus Gemtuzumab Ozogamicin**

Inclusion Criteria:
A signed informed consent / Newly diagnosed CD33-positive AML with NPM1 mutation according to WHO criteria / Age 18-70 years / Fit for intensive chemotherapy, defined by_ ECOG performance status of 0-2 / Adequate hepatic function: ALAT/ASAT/Bilirubin ≤ 2.5 x ULN unless considered due to leukemic organ involvement Note: Subjects with Gilbert's Syndrome may have a bilirubin > 2.5 × ULN per discussion between the investigator and Coordinating investigator. / Adequate renal function assessed by serum creatinine ≤ 1.5x ULN OR creatinine clearance (by Cockcroft Gault formula) ≥ 50 mL/min / WBC < 25 x 109/L (<25,000/µL), prior hydroxyurea is permitted to meet this criterion / Ability to understand and the willingness to sign a written informed consent. / Male subjects must agree to refrain from unprotected sex and sperm donation from time point of signing the informed consent until 7 months after the last dose of study drug. / Women of childbearing potential must have a negative serum or urine pregnancy test performed within 72 hours before first dose of study drug..
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT05904106

Study Test Center	PI / SC	Phone	E-Mail
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Multicenter, Open-label, Randomized, Phase 2 Study of Venetoclax and Azacitidine Plus Cusatuzumab Versus Venetoclax and Azacitidine Alone in Newly Diagnosed AML Patients Who Are Not Candidates for Intensive Therapy

Condition: Acute Myeloid Leukemia
Primary Completion Date: 2027-01
Phase: II
Intervention/ Treatment: DRUG: **Cusatuzumab/ Venetoclax/ Azacitidine**

Inclusion Criteria:
Men and women ≥18 years old / Must sign an informed consent form (ICF) indicating that he or she understands the purpose of, and procedures required for the study and is willing to participate in the study / Diagnosis of AML according to ICC 2022 (with the exclusion of MDS/AML with 10-19% blasts) / Previously untreated AML except may have received emergency leukapheresis, hydroxyurea before study entry to control hyperleukocytosis / Deemed unfit for intensive chemotherapy by meeting **at least 1 of the following criteria:** Participant is ≥75 years of age with Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 **OR Participant is ≥18 to 74 years of age and has any of the following comorbidities:** ECOG performance status of 2 or 3 / Cardiac status including any one of the following: congestive heart failure requiring treatment or ejection fraction ≤50% or chronic stable angina / Known history of diffusion capacity of lung for carbon monoxide (DLCO) ≤65% of forced expiratory volume in the first second (FEV1) ≤65% / Creatinine clearance (CrCl) ≥15 mL/min to <45 mL/min / Hepatic disorder with total bilirubin >1.5 to 3x the upper limit of normal (ULN) / Any other comorbidity that the investigators determine to be incompatible with conventional intensive chemotherapy / **Adequate liver and renal function defined as:** Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) <3xULN; for participants with leukemic infiltration of the liver (documented by biopsy or imaging), AST and ALT <5xULN is permitted / Total bilirubin ≤1.5xULN, unless bilirubin rise is due to Gilbert's syndrome or of nonhepatic origin. Participants who are <75 years of age may have a bilirubin up to 3xULN. / Estimated glomerular filtration rate (eGFR) ≥30 mL/min/1.73 m2 (by the Modification of Diet in Renal Disease [MDRD] formula). Participants who are <75 years of age may have an eGFR ≥15 mL/min/1.73 m2. / Women of childbearing potential (WOCBP), defined as fertile women between menarche /and post menopause unless permanently sterile, must have a negative highly sensitive serum β-human chorionic gonadotropin (β-hCG) or urine pregnancy test at screening / Must be willing to use contraception as consistent with institutional guidelines regarding the use of contraceptive methods for participants participating in clinical studies / WOCBP must agree to adhere to the following birth control measures while receiving study treatment continuing to 3 months after the last dose of study drug: / Must be practicing a highly effective method of birth control (failure rate of <1% per year when used consistently and correctly) as determined by institutional standards / Must agree to not donate eggs (ova, oocytes) for the purposes of assisted reproduction / Must not be breastfeeding and not planning to become pregnant / Male participants who are sexually active with WOCBP, and male partners of study participants who are WOCBP, and who are not surgically or otherwise sterile must agree to adhere to the following birth control measures while receiving study treatment and for 3 months after the last dose of study drug: / Must agree to use a barrier method of birth control (e.g., either condom with spermicidal foam/gel/film/cream/suppository or partner with occlusive cap [diaphragm or cervical/vault caps] with spermicidal foam, gel, film, cream, or suppository) / Must not donate sperm / Must no plan to father a child / Participants with HIV infection are eligible for the trial if the following criteria are met: CD4+ T-cell count ≥200 cells/µL / No prior history of AIDS-defining opportunistic infection within the past 12 months / Receiving treatment with antiretroviral therapy / Undetectable viral load within 6 months of screening

Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT05904106

Study Test Center	PI / SC	Phone	E-Mail
UKSH Kiel Medical Clinic II	Dr. med. Lars Fransecky Ann-Katrin Fichte	0431 500 22515 0431 500 22569	Lars.Fransecky@uksh.de Ann-Katrin.Fichte@uksh.de

Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Randomized, Placebo-Controlled Phase III Study of Induction and Consolidation Chemotherapy With Venetoclax in Adult Patients With Newly Diagnosed Acute Myeloid Leukemia or Myelodysplastic Syndrome With Excess Blasts-2

Condition: Acute Myeloid Leukemia, Myelodysplastic Syndromes
Primary Completion Date: 2025-02-01
Phase: I/II
Intervention/ Treatment: DRUG: **Venetoclax / Placebo**_COMBINATION PRODUCT: **Standard chemotherapy**_ OTHER: **Autologous stem cell transplantation/ Allogeneic stem cell transplantation**

Inclusion Criteria:
Patients with newly diagnosed acute myeloid leukemia (AML), or myelodysplastic syndrome with excess blasts-2 (MDS-EB2) according to World Health Organization (WHO) classification. / Age ≥ 18 years, no upper age limit. / Patient considered eligible for intensive chemotherapy. / Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2 at randomization. / Molecular analysis centrally performed in AMLSG and HOVON laboratories. / Adequate renal function as evidenced by serum creatinine ≤ 2.0 × upper limit of norm (ULN) or creatinine clearance >40 mL/min based on the Cockcroft-Gault glomerular filtration rate (GFR). / Adequate hepatic function as evidenced by:Serum total bilirubin ≤ 2.5 × ULN unless considered due to Gilbert's disease, or leukemic involvement following approval by the Coordinating Investigator or Trial Coordinator / Aspartate aminotransferase (AST), alanine aminotransferase (ALT), and alkaline phosphatase (ALP) ≤ 3.0 × ULN, unless considered due to leukemic involvement following approval by the Coordinating Investigator or Trial Coordinator / No prior chemotherapy for AML except hydroxyurea for up to 14 days during the diagnostic screening phase for the control of peripheral leukemic blasts in patients with leukocytosis (e.g., white blood cell [WBC] counts > 25x109/L); patients may have had previous treatment with erythroid stimulating agents (ESA) or hypomethylating agents (HMAs) for an antecedent phase of MDS; ESA and HMAs have to be stopped at least four weeks before enrolment. / Subjects must not have received a known strong or moderate CYP3A inducer 7 days before enrolment. Subjects must have no known medical conditions requiring chronic therapy with moderate or strong CYP3A inducers. / **Female patient must either:** Be of nonchildbearing potential: Postmenopausal (defined as at least 1 year without any menses) / Documented surgically sterile or status posthysterectomy (at least 1 month prior to screening) / Or, if of childbearing potential (not surgically sterile (e.g. documented hysterectomy, bilateral oophorectomy, bilateral salpingectomy or congenital sterile) and not postmenopausal) / Not planning to become pregnant during the study and for 6 months after the final study drug administration / And have a negative urine or serum pregnancy test at screening / And, if heterosexually active, agree to consistently apply one highly effective* in combination to a barrier method for the duration of the study and for 6 months after the final study drug administration / *Highly effective forms of birth control include / Consistent and correct usage of established hormonal contraceptives that inhibit ovulation (hormonal contraception is only a highly effective method of birth control, if a combined [estrogen and progestogen containing] hormonal contraception or a progestogen-only hormonal contraception - both associated with inhibition of ovulation - is used. / Established intrauterine device (IUD) or intrauterine system (IUS) / Bilateral tubal occlusion / Vasectomy - a vasectomy is highly effective contraception method provided the absence of sperm has been confirmed. If not, an additional highly effective method of contraception should be used. / Male is sterile due to a bilateral orchiectomy. / Sexual abstinence is considered a highly effective method only if defined as refraining from heterosexual activity during the entire period of risk associated with the study drug. The reliability of sexual abstinence needs to be evaluated in relation to the duration of the clinical study and the preferred and usual lifestyle of the patient. / *List is not all inclusive. Prior to enrolment, the investigator is responsible for confirming patient will utilize highly effective forms of birth control in combination with a barrier method according to locally accepted standards during the protocol defined period. / Female patient must agree not to breastfeed starting at screening and throughout the study period, and for 2 months and 1 week after the final study drug administration. / Female patient must not donate ova starting at screening and throughout the study period, and for 6 months after the final study drug administration. / Men must use a latex condom during any sexual contact with WOCBP, even if they have undergone a successful vasectomy and must agree to avoid to father a child (while on therapy and for 6 months after the final study drug administration). In addition, their female partners of childbearing potential have to use a highly effective method of birth control. / Male patient must not donate sperm starting at screening and throughout the study period and for 6 months after the final study drug administration. / Able to understand and willing to sign an informed consent form (ICF).

Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT04628026

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Phase Ia/IIb study of PHD inhibitor molidustat in combination with IDH1 inhibitor ivosidenib in IDH1-mutated relapsed/refractory AML or MDS/AML patients

Condition: Myelodysplastic syndrom
Primary Completion Date: ongoing
Phase: I/II
Intervention/ Treatment: DRUG: **Ivosidenib**

Inclusion Criteria:
Age ≥ 18 years. / Patients with diagnosis of relapsed/refractory AML or relapsed/refractory MDS/AML with 10-19% bone marrow blasts at initial diagnosis and at screening defined according to 2022 ICC criteria after at least one prior line of treatment who are ineligible for intensive salvage chemotherapy and/or allogeneic hematopoietic cell transplantation or who decline standard treatment. / IDH1-mutated as determined by a validated assay at a specific site (IDH1 R132). / ECOG 0-2. / Adequate hepatic function as evidenced by: • Serum total bilirubin ≤ 3 × upper limit of normal (ULN) unless considered due to Gilbert's syndrome, or leukemic involvement of the liver – following written approval by the Principal Investigator. • Aspartate aminotransferase (AST) and alanine aminotransferase (ALT), ≤ 3.0 × ULN, unless considered due to leukemic involvement of the liver, following written approval by the Principal Investigator. / Adequate renal function as eFemalevidenced by creatinine clearance ≥ 30 mL/min based on the CKD-EPI formula for glomerular filtration rate (GFR). / Able to understand and willing to sign an informed consent form (ICF). / Written informed consent. / patient must either: • Be of non-childbearing potential: o Postmenopausal prior to screening defined as: □ ≥ 50 years and in postmenopausal state > 1 year or □ < 50 years and in postmenopausal state > 1 year with serum FSH > 40 IU/l and serum estrogen < 30 ng/l or a negative estrogen test, both at screening or o Documented surgically sterile by bilateral tubal ligation or bilateral oophorectomy or status post-hysterectomy or uterine agenesis (at least 1 month prior to screening).• **If of childbearing potential:** o Agree not to try to become pregnant during the study and for 6 months after the final study drug administration o And have a negative serum pregnancy test at screening o And, if heterosexually active, agree to consistently use highly effective* contraception per locally accepted standards in addition to a barrier method starting at screening and throughout the study period and for 6 months after the final study drug administration. / * Highly effective forms of birth control include: i. Established intrauterine device (IUD) or intrauterine system (IUS). ii. Bilateral tubal occlusion. iii. Vasectomy (A vasectomy is a highly effective contraception method provided the absence of sperm has been confirmed. If not, an additional highly effective method of contraception should be used). iv. Male is sterile due to a bilateral orchiectomy. v. Sexual abstinence is considered a highly effective method only if defined as refraining from heterosexual activity during the entire period of risk associated with the study drug. The reliability of sexual abstinence needs to be evaluated in relation to the duration of the clinical study and the preferred and usual lifestyle of the patient. * List is not all inclusive. Prior to enrollment, the investigator is responsible for confirming patient will utilize highly effective forms of birth control per the requirements of the CTFG Guidance document 'Recommendations related to contraception and pregnancy testing in clinical trials', September 2020 (and any updates thereof) during the protocol defined period. Since ivosidenib may decrease the concentrations of hormonal contraceptives, it is considered to use alternative methods of contraception as mentioned above (see section 5.5). • Female patient must agree not to breastfeed starting at screening and throughout the study period, and for 2 months after the final study drug administration. • Female patient must not donate ova starting at screening and throughout the study period, and for 6 months after the final study drug administration. 10. Male patient and their female partners who are of childbearing potential must be using highly effective contraception per locally accepted standards (see above *highly effective forms of birth control) in addition to a barrier method starting at screening and continue throughout the study period and for 4 months and 1 week after the final study drug administration. 11. Male patient must not donate sperm starting at screening and throughout the study period and for 4 months and 1 week after the final study drug administration. 12. Patient agrees not to participate in another interventional study while on treatment. 13. Ability to swallow and retain oral medication, no known malabsorption syndrome, adequate organ function.

Exclusion Criteria:
see Link:

clinicaltrialsregister.eu:2021-006895-17

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
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A Phase 1 Single-Arm, Open-Label Study of CA-4948 in combination with Azacitidine and Venetoclax in Acute Myeloid Leukemia Patients in complete response with measurable Residual Disease

Condition: Primary or secondary AML
Primary Completion Date:
Phase: I
Intervention/ Treatment: DRUG: **Emavusertib/ Azacitidine/ Venetoclax**

Inclusion Criteria:
Aged ≥60 years / Confirmed diagnosis of AML (primary or secondary) by World Health Organization criteria per medical record and: **a.** ongoing treatment with azacitidine + venetoclax as first-line treatment for no more than 6 cycles / **b.** achieved documented CR as described in Appendix B or CRh (Bloomfield, et al 2018) within 28 days (+ 3-day window) prior to C1D1 / **c.** must have documented bone marrow MRD positivity (local laboratory) within 28 days (+ 3-day window) prior to C1D1 / **d.** without known Grade ≥2 toxicity related to treatment with azacitidine + venetoclax / **e.** not immediate candidate for allogeneic stem cell transplant / Eastern Cooperative Oncology Group (ECOG) Performance Status ≤2 / Acceptable organ function at screening as described below: / a. estimated creatinine clearance of ≥35 mL/minute / **b.** AST or ALT ≤2 × ULN / **c.** total bilirubin ≤1.5 × ULN or ≤3 × ULN in patients with documented Gilbert's syndrome / **d.** Absolute neutrophil count >0.5 × 109/L and platelets >50 × 109/L
5. Creatine phosphokinase <2.5 × ULN / 6. Negative serum pregnancy test in women of childbearing potential (WOCP) / 7. For patients on a cholesterol-lowering agent that has been associated with CPK elevations, such as statins or fibrates, the agent should be discontinued or replaced with an alternative if medically feasible. Otherwise, it should be reduced to a minimally effective dose.
8. Ability to swallow and retain oral medications. / 9. WOCP and men with sexual partners who are WOCP: agree to use highly effective contraceptive methods for the duration of the study and for 180 days after the last dose of emavusertib. / 10. Willing and able to provide written informed consent and comply with the requirements of the study. / 11. Amenable to serial bone marrow sampling and peripheral blood sampling during the study.

Exclusion Criteria:
Individuals who meet any of the following exclusion criteria will not be eligible to participate in this study / 1. Known active central nervous system (CNS) leukemia; patients with previously treated CNS disease may participate if asymptomatic as determined by treating physician (without symptomatic active disease for at least 4 weeks prior to C1D1, and any neurologic symptoms have returned to baseline) / 2. Documented BCR-ABL positive AML or chronic myeloid leukemia (CML) including blast crisis of CML or acute promyelocitic leukaemia. / 3. Investigational agents, immunomodulatory therapy, and anti-cancer agents, with the exception of azacitidine and venetoclax, are prohibited for 28 days (or 5 half-lives), whichever is shorter, before C1D1 and throughout the duration of the study treatment. /
4. Allogeneic SCT within 60 days of the first dose of emavusertib / 5. Presence of any non-hematological Grade 3 toxicity that has not resolved to Grade ≤2. Presence of any Grade 2 acute or chronic toxicity resulting from prior anti-cancer therapy that has not resolved to Grade ≤1 (with the exception of alopecia), as determined by NCI-CTCAE version 5.0, within 7 days prior to C1D1. / 6. Major surgery, other than diagnostic surgery, <28 days prior to C1D1; minor surgery <14 days prior to C1D1.

see Link:

euclinicaltrials.eu: 2023-505828-58-00

Study Test Center	PI / SC	Phone	E-Mail
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Chronic lymphocytic leukemia (CLL)

continue...

Contact at UCC Hamburg
Dr. med. Minna Voigtländer, Tel. 0152 228 179 11 (CLL)

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Study on Venetoclax, Obinutuzumab, and Pirtobrutinib for Patients with Untreated Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma

Condition: Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma
Primary Completion Date: N/A
Phase: III
Intervention/ Treatment: DRUG: **Venetoclax/ Obinutuzumab**

Inclusion Criteria:
Must have a documented diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) that requires treatment. / Must have adequate bone marrow function, which means:An absolute neutrophil count (a type of white blood cell) of at least 1 x 109/L.A hemoglobin level (a protein in red blood cells) of at least 8.0 g/dL without needing a blood transfusion in the last 7 days, unless the low level is directly due to CLL/SLL.A platelet count (cells that help with blood clotting) of at least 25 x 109/L, unless the low count is due to CLL/SLL, in which case it should be at least 10,000/µL without a transfusion in the last 7 days.Must have adequate kidney function, shown by a creatinine clearance (a measure of kidney function) of at least 30 ml/min.Must have adequate liver function, which means:Total bilirubin (a substance made by the liver) should be no more than 2 times the normal upper limit, unless due to CLL/SLL or Gilbert’s Syndrome.AST/ALT (liver enzymes) should be no more than 2.5 times the normal upper limit, unless due to CLL/SLL / Must test negative for hepatitis B, hepatitis C, and HIV within 6 weeks before joining the study / Must be at least 18 years old / Must have an Eastern Cooperative Oncology Group (ECOG) Performance Status, which is a measure of daily living abilities / Must have a life expectancy of at least 6 months / Must be able and willing to provide written informed consent and follow the study visit schedule and other requirements.

Exclusion Criteria:
Patients with any other type of cancer that is not **chronic lymphocytic leukemia (CLL)** or **small lymphocytic lymphoma (SLL)** cannot participate. / Patients who have previously received treatment for **CLL** or **SLL** are not eligible. / Patients with severe heart problems, such as heart failure or recent heart attack, are excluded. / Patients with uncontrolled high blood pressure cannot join the study. / Patients with active infections that require treatment with antibiotics, antifungals, or antivirals are not allowed. / Patients with a history of other serious medical conditions that could interfere with the study are excluded. / Pregnant or breastfeeding women cannot participate in the study.Patients who are unable to follow the study procedures or comply with the study requirements are not eligible.
see Link:

euclinicaltrials.eu:2023-510294-34-00

Study Test Center	PI / SC	Phone	E-Mail
UKE MEDICAL ONCOLOGY	Dr. med. Minna Voigtländer Anna Laura Rodemeister (SC)	0152 228 179 11 040-7410 54729	m.voigtlaender@uke.de a.rodemeister@uke.de

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A Phase 3 Randomized, Double-blind, Placebo-controlled, Study of Bleximenib, Venetoclax and Azacitidine for the Treatment of Participants with Newly Diagnosed Acute Myeloid Leukemia Harboring *KMT2A* Rearrangements or *NPM1* Mutations who are Ineligible for Intensive Chemotherapy

Condition: Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma
Primary Completion Date: 2029-08-15
Phase: III
•**Intervention/ Treatment:** DRUG: **Bleximenib/ Venetoclax (VEN)/ Azacitidine (AZA)/ Placebo**

Inclusion Criteria:
Be 18 years of age or older at the time of informed consent / Previously untreated lysine N-methyltransferase 2A gene rearranged (KMT2Ar) or nucleophosmin 1 gene mutated (NPM1m) acute myeloid leukemia (AML) with greater than or equal to (> or =) 10% bone marrow blasts per 2022 international Consensus Classification criteria / Ineligible for intensive chemotherapy based on the following criteria: a) >= 75 years of age and ineligible per physician's discretion, with Eastern Cooperative Oncology Group (ECOG) performance status of 0-2, b) >=18 to <75 years of age with >= 1 of the following comorbidities: i) ECOG performance status of 2, ii) Severe cardiac disorder, iii) Severe pulmonary disorder, iv) Renal impairment, v) Moderate hepatic impairment vi) Comorbidity that, in the investigator's opinion, makes the participant unsuitable for intensive chemotherapy, which must be documented before enrollment as defined in the protocol. Ineligibility for intensive chemotherapy should be explicitly approved by a multidisciplinary team in countries in which this process is standard of care / Participants must have adequate hepatic and renal function / A female participant must agree not to be pregnant, breast-feed, plan to become pregnant and use protocol-specified contraception while enrolled in this study and for 6 months after the last dose of study treatment / A male participant must agree to use protocol-specified contraception while enrolled in this study for at least 90 days after the last dose of study treatment / Must sign an informed consent form indicating that the participant understands the purpose of, and procedures required for, the study and is willing to participate in the study

Exclusion Criteria:
Diagnosis of acute promyelocytic leukemia (APL) / Known active leukemic involvement of the central nervous system (CNS) / Recipient of solid organ transplant / Any cardiac disorders such as heart attack, uncontrolled/unstable chest pain, congestive heart failure, uncontrolled or symptomatic irregular heartbeat, blockage of a blood vessel to brain, or transient ischemic (decreased oxygen in tissue) attack within 6 months of randomization / Active infectious hepatitis / Live, attenuated vaccine within 4 weeks of randomization / Known allergies, hypersensitivity, or intolerance of bleximenib, azacitidine, or venetoclax excipients

see Link: N/A

clinicaltrials.gov/NCT06852222

Study Test Center	PI / SC	Phone	E-Mail
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A Prospective, Open-label, Multicenter Phase-II Trial to Evaluate the Efficacy and Safety of Zanubrutinib (BGB-3111), a BTK Inhibitor, Plus Tislelizumab (BGB-A317), a PD1 Inhibitor, for Treatment of Patients with Richter Transformation with or Without Sonrotoclax（ BGB-11417), a Bcl-2 Inhibitor (CLL-RT1-trial of the GCLLSG).

Condition: Richter Transformation
Primary Completion Date: 2026-08
Phase: II
Intervention/ Treatment: DRUG: **Zanubrutinib/ Sonrotoclax**_BIOLOGICAL: **Tislelizumab**

Inclusion Criteria:
Confirmed diagnosis of CLL according to iwCLL criteria (Hallek et al, 2018) / Confirmed histopathological diagnosis of RT (diffuse large B-cell lymphoma or Hodgkin's lymphoma [Hodgkin's lymphoma only when not eligible for more in-tensive treatment]) / Previously untreated RT or patients with objective response or non-tolerance to first-line RT treatment / **Adequate bone marrow function as defined by:** Absolute neutrophil count (ANC) ≥ 1000/mm3, except for patients with bone marrow involvement in which ANC must be ≥ 500/mm3_Platelet ≥ 75,000/mm3, except for patients with bone marrow involvement in which the platelet count must be ≥ 30,000/mm3 / Creatinine clearance ≥30ml/min calculated according to the modified formula of Cockcroft and Gault or directly measured with 24hr urine collection or an equivalent method. / Adequate liver function as indicated by a total bilirubin≤ 2 x, AST/ALT ≤ 2.5 x the institutional ULN value, unless directly attributable to the patient's CLL/RT or to Gilbert's Syndrome, in which case a max. total bilirubin ≤ 3 x and AST/ALT ≤ 5 x the institutional ULN value are required. / Negative serological testing for hepatitis B (HBsAg negative and anti-HBc nega-tive; patients positive for anti-HBc may be included if PCR for HBV DNA is negative and HBV-DNA PCR is performed every two months until 2 months af-ter last dose of zanubrutinib), negative testing for hepatitis-C RNA and negative HIV test within 6 weeks prior to registration / Age at least 18 years / ECOG performance status 0-2, ECOG 3 is only permitted if related to CLL or RT (e.g. due to anaemia or severe constitutional symptoms) / Life expectancy ≥ 3 months / Ability and willingness to provide written informed consent and to adhere to the study visit schedule and other protocol requirements
Exclusion Criteria:
see Link: N/A

clinicaltrials.gov/NCT04271956

Study Test Center	PI / SC	Phone	E-Mail
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A Phase 1b/2, Open-Label, Safety and Efficacy Study of Epcoritamab (GEN3013; DuoBody®-CD3xCD20) in Relapsed/Refractory Chronic Lymphocytic Leukemia and Richter's Syndrome

Condition: Relapsed/Refractory Chronic Lymphocytic Leukemia/ Small Lymphocytic Lymphoma/ Richter's Syndrome/ Treatment-naïve High Risk Chronic Lymphocytic Leukemia
Primary Completion Date: 2029-06
Phase: I/II
Intervention/ Treatment: DRUG: **Rituximab/ Cyclophosphamide/ Doxorubicin/ Vincristine/ Prednisone/ Venetoclax/ Lenalidomide/ Pirtobrutinib**_Biological: **Epcoritamab**

Inclusion Criteria:
Eastern Cooperative Oncology Group (ECOG) performance status score of 0, 1 or 2. / Evidence of CD20 positivity in a sample representative of the disease at Screening. / Acceptable hematology parameters and organ function based on baseline bloodwork. / Life expectancy >3 months on standard of care (SOC) for CLL, >3 months for RS. / For R/R CLL arms - Must have active CLL/SLL disease requiring treatment per iwCLL 2018 criteria. / For R/R CLL monotherapy arms - Received at least 2 prior lines of systemic anti-neoplastic therapy including a Bruton's tyrosine kinase (BTK) inhibitor or at least 1 prior line of systemic antineoplastic therapy, including treatment with (or intolerance of) a covalent BTK inhibitor (cBTKi) and a B-cell lymphoma 2 (BCL-2) inhibitor. / For all RS arms - Have tumor biopsy-proven CD20+ Diffuse large B-cell Lymphoma (DLBCL) and a clinical history of CLL/SLL. / Must have measurable disease by fluorodeoxyglucose-positron emission tomography (FDG-PET) and computed tomography (CT) or magnetic resonance imaging (MRI) scan. / Must provide mandatory formalin-fixed, paraffin-embedded (FFPE) tumor biopsy sample. / For RS - monotherapy arm: Deemed as ineligible for chemoimmunotherapy at investigator's discretion or participant who refuses to receive intensive chemotherapy / For RS - lenalidomide combination therapy arm: Deemed as ineligible for chemoimmunotherapy at the investigator's discretion, or participant who refuses to receive intensive chemotherapy. / Eligible for treatment with lenalidomide. / Must be willing to use contraception and adhere to the Lenalidomide Pregnancy Risk Minimization Plan / A woman must agree not to breastfeed a child during treatment and for at least 28 days after discontinuation from study. /
For RS - R-CHOP combination Therapy Arm: Eligible for treatment with R-CHOP. / Females of childbearing potential must use highly effective contraceptive measures while taking R-CHOP and for 12 months after stopping treatment. / A woman must agree not to breastfeed a child during treatment or until 12 months after last treatment. / For R/R CLL - venetoclax combination Therapy arm: after receiving at least 1 prior line of systemic antineoplastic therapy. / Presence of measurable disease. / Must take prophylaxis for tumor lysis syndrome (TLS). / For R/R CLL pirtobrutinib combination Therapy arm: Must have active CLL/SLL disease requiring treatment per iwCLL 2018 criteria. / Presence of measurable disease. / Previous treatment with at least one and a maximum 3 prior lines of therapy including a cBTKi / Diagnosis of CLL/SLL that met published iwCLL criteria. / Non-US Participants Only / Participants with TN HR CLL / Pirtobrutinib Combination Therapy Expansion: Diagnosis of CLL/SLL that met published iwCLL criteria 2018. / Must have active CLL/SLL disease that needs treatment per iwCLL / Must take prophylaxis for TLS based on their TLS risk evaluation upon initiation of trial drug. / Must have one or more high-risk features. / Presence of measurable disease.
Exclusion Criteria:
see Link: N/A

clinicaltrials.gov/NCT04623541

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
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25c

„CLL16“

This multicenter, prospective, open-label, randomized, superiority phase 3 study is designed to demonstrate that treatment with a triple combination of acalabrutinib, obinutuzumab and venetoclax (GAVe) prolong the progression-free survival (PFS) as compared to treatment with the combination of obinutuzumab and venetoclax (GVe) in pa-tients with high risk CLL (defined as having at least one of the follow-ing risk factors: 17p-deletion, TP53-mutation or complex karyotype).

Condition: Chronic Lymphocytic Leukemia
Primary Completion Date: 2026-05
Phase: III
Intervention/ Treatment: DRUG: **Obinutuzumab/ Venetoclax/ Acalabrutinib**

Inclusion Criteria:
Documented CLL/SLL requiring treatment according to iwCLL criteria / Age at least 18 years / At least one of the following risk factors: 17p-deletion, TP53-mutation or complex karyotype (defined as defined as the presence of 3 or more chromosomal aberrations in 2 or more metaphases.). / Life expectancy ≥ six months / Adequate bone marrow function indicated by a platelet count >30 x10^9/l / Creatinine clearance ≥ 30ml/min / Adequate liver function as indicated by a total bilirubin ≤ 2 x, AST/ ALT ≤ 2.5 x the institutional ULN value, unless directly attributable to the patient's CLL or to Gilbert's Syndrome Negative testing for hepatitis B (HbsAg negative and anti-HBc negative; patients positive for anti-HBc may be included if PCR for HBV DNA is negative and HBV-DNA PCR is performed every month until 12 months after last treatment cycle),or hepatitis C (negative testing for hepatitis C RNA within 6 weeks prior to registration for study screening (i.e. PCR only required when serology was positive))
ECOG (Eastern Cooperative Oncology Group Performance Status) status 0-2

Exclusion Criteria:
Any prior CLL-specific therapies (except corticosteroid treatment administered due to necessary immediate intervention; within the last 10 days before start of study treatment, only dose equivalents up to 20 mg prednisolone are permitted) / Absence of high risk disease (17p-deletion, TP53-mutation complex karyotype / An individual organ/system impairment score of 4 as assessed by the CIRS definition (e.g. advanced cardiac disease (NYHA class 3 or 4) limiting the ability to receive the study treatment or any other life-threatening illness, medical condition or organ system dysfunction that, in the investigator´s opinion, could compromise the patients safety or interfere with the absorption or metabolism of the study drugs (e.g. inability to swallow tablets or impaired resorption in the gastrointestinal tract) Transformation of CLL (Richter transformation) / Malignancies other than CLL currently requiring systemic therapies / Uncontrolled or active infection of HIV/PML or any other active infection Anticoagulant therapy with warfarin or phenoprocoumon / Pregnant women and nursing mothers
see Link:

clinicaltrials.gov/NCT05197192

Study Test Center	PI / SC	Phone	E-Mail
UKE Medical Oncology	Dr. med. Minna Voigtländer Alexandra Pfeffer (SC)	0152 228 179 11 040-7410 58073	m.voigtlaender@uke.de a.pfeffer@uke.de
Oncoresearch Lerchenfeld (Hamburg)	Regina Waldeck (SC)	040 22604650	r.waldeck@oncoresearch-lerchenfeld.de
UKSH Kiel II. Medical Clinic	Dr. med. Matthias Ritgen Gunda Heydorn-Heistermann (SC)	0431 500 22511 0431 500 22561	Matthias.Ritgen@uksh.de Gunda.Heydorn-Heistermann@uksh.de

Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Multicenter, Open-Label, Phase 2 Study to Evaluate the Efficacy and Safety of Venetoclax-Obinutuzumab Retreatment in Patients With Recurring Chronic Lymphocytic Leukemia

Condition: Chronic Lymphocytic Leukemia (CLL)
Primary Completion Date: 2025-02-22
Phase: II
Intervention/ Treatment: Drug: **Venetoclax/ Obinutuzumab**

Inclusion Criteria:
Documented diagnosis of chronic lymphocytic leukemia (CLL) that requires treatment for CLL according to International Workshop for Chronic Lymphocytic Leukemia (iwCLL) 2018 criteria.
Previously completed venetoclax + anti-CD20 antibody +/- X regimen as a fixed duration first-line (1L) therapy and achieved documented response, defined as complete remission, complete remission with incomplete marrow recovery, partial remission, or nodular partial remission. / More than 24 months (Cohort 1) or 12-24 months (Cohort 2) have elapsed between last dose of venetoclax and disease progression after completion of 1L treatment.
Exclusion Criteria:
Received intervening treatment for CLL after completing previous treatment with a venetoclax + anti-CD20 antibody +/- X regimen.
see Link:

clinicaltrials.gov/NCT04895436

Study Test Center	PI / SC	Phone	E-Mail
Oncoresearch Lerchenfeld	Frau R. Waldeck (Coordination)	040-22604650	r.waldeck@oncoresearch-lerchenfeld.de

A Phase I/II Open-Label Multi-Centre Master Protocol to Evaluate the Safety and Efficacy of AZD0486 Monotherapy or in Combination With Other Anticancer Agents in Participants With Mature B-Cell Malignancies

Condition: Chronic Lymphocytic Leukaemia/ Small Lymphocytic Lymphoma/ Mantle-cell Lymphoma/ Large B-cell Lymphoma/ B-cell Non-Hodgkin Lymphoma
Primary Completion Date: 2028-02-28
Phase: I/II
Intervention/ Treatment: Drug: **AZD0486/ Prednisone (or equivalent)/ Rituximab/ Cyclophosphamide/ Vincristine/ Doxorubicin/ Acalabrutinib**

Inclusion Criteria:
Master Inclusion Criteria applicable to all substudies:
Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2. / Contraception use during treatment and at least 90 days after final dose. / Confirmed CD19 expression if prior anti-CD19 therapy. / **Substudy 1 Specific Inclusion Criteria:** Participants with CLL must require treatment according to the international workshop on Chronic Lymphocytic Leukemia (iwCLL) criteria. / SLL: at least 1 measurable site per Lugano. / Absolute lymphocytes <10,000. / Cohort 1A and 1C: at least 2 prior lines of systemic therapy for CLL/SLL. / Cohort 1B: at least 1 prior line of therapy and is bruton tyrosine kinase inhibitor (BTKi)-sensitive. / **Substudy 2 Specific Inclusion Criteria:** MCL diagnosis per WHO. / Clinical Stage II, III, or IV by Ann Arbor Classification. / At least 1 measurable site per Lugano. / ALC < 10,000. / Cohort 2A and 2C: Relapse or progressed after 2 or more lines of therapy including BTKi. / **Substudy 3 Specific Inclusion Criteria:** Large B-cell lymphoma per WHO 2022. / R/R B-NHL after at least 1 prior line of therapy. / International Prognostic Index (IPI) 2-5. / At least 1 measurable site as per Lugano. / Left ventricular ejection fraction (LVEF) >50%. / Contraception at least 90 days after last dose of AZD0486 or 4 months after last dose of vincristine, and 6 months after the last dose of cyclophosphamide, or doxorubicin.
Exclusion Criteria: .
see Link:

clinicaltrials.gov/NCT06564038

Study Test Center	PI / SC	Phone	E-Mail
UKSH Kiel Medical Clinic II	Prof. Dr. med. Christiane Pott Gunda Heydorn-Heistermann (SC)	0431 500 22516 0431 500 22561	Christiane.Pott@uksh.de Gunda.Heydorn-Heistermann@uksh.de

Prospective randomized multicenter phase III trial of decitabine and venetoclax administered in combination with all-trans retinoic acid or placebo in patients with acute myeloid leukemia who are ineligible for induction chemotherapy

Condition: Myeloid leukaemia
Primary Completion Date: N/A
Phase: I/II
Intervention/ Treatment: Drug: **DAC/ VEN/ ATRA/ Placebo**

Inclusion Criteria:
Sex: All / Minimum Age: 18 Years / Maximum Age: 99 Years / Age ≥ 18 years / Previously untreated AML (WHO 2016) / ECOG ≤ 2 / White blood cell count < 25 × 109/L (hydroxyurea or Ara-C are permitted to meet this criterion see section 6.6.2) / Patients for whom standard intensive induction chemotherapy is not feasible, patients not considered to benefit from standard intensive induction chemotherapy; the following criteria are generally accepted (examples) / age ≥ 75 years / ECOG ≥ 1 / HCT-CI ≥ 3 / adverse genetics / patient declines standard aggressive chemotherapy / missing social support system6. Projected life expectancy of at least 8 weeks / Written informed consent obtained according to international guidelines and local laws / Ability to understand the nature, significance and consequences of the trial and the trial related procedures and to comply with them
Exclusion Criteria:
see Link:

Drks.de: DRKS00023646

Study Test Center	PI / SC	Phone	E-Mail
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Chronic myeloid leukemia (CML)

continue...

Contact at UCC Hamburg
Dr. med. Philippe Schafhausen, Tel: 040 7410-57122 (MDS & CML)

Currently no study options

continue...

Randomized, Open-label, Multicenter Phase 3 Study to Assess the Efficacy and Safety of GIVinostat Versus Hydroxyurea IN JAK2V617F-positive High-risk Polycythemia Vera Patients: the GIV-IN PV TRIAL

Condition: Steroid-refractory Acute Graft-versus-host Disease
Primary Completion Date: 2027-08
Phase: III
Intervention/ Treatment: BIOLOGICAL: **MC0518/ BAT**

Inclusion Criteria:
Participant had a previous allogeneic HSCT as indicated for non-malignant (including inborn errors of metabolism, primary immunodeficiencies, haemoglobinopathies, and bone marrow failure syndromes) or haematological malignant disease, irrespective of human leukocyte antigen match / Participant has been clinically diagnosed with Grade II to IV aGvHD at the Screening Visit / Participant has experienced failure of previous first-line aGvHD treatment (ie, SR-aGvHD), defined as: a) aGvHD progression within 3 to 5 days of therapy onset with >= 2 mg/kg/day of prednisone equivalent or b) failure to improve within 5 to 7 days of treatment initiation with >= 2 mg/kg/day of prednisone equivalent or c) incomplete response after > 28 days of immunosuppressive treatment including at least 5 days with >= 2 mg/kg/day of prednisone equivalent / Participant has an estimated life expectancy > 28 days at the Screening Visit / Male or female participant who is >= 12 years of age at the Screening Visit
Exclusion Criteria:
Inclusion Criteria:
Participant has overt relapse or progression or persistence of the underlying disease at the Screening Visit / Participant has received the last HSCT for a solid tumour disease / Participant has GvHD overlap syndrome at the Screening Visit / Participant has received systemic first line treatment for aGvHD other than steroids and a prophylaxis with other than calcineurin inhibitors, mammalian target of rapamycin (mTOR) inhibitors, anti-thymocyte globulin (ATG), mycophenolate mofetil (MMF), methotrexate (MTX), and / or cyclophosphamide before the Screening Visit / Participant has a known pregnancy (as confirmed by a positive pregnancy test at the Screening Visit) and or is breastfeeding at the Screening Visit / Participant has received treatment with any other investigational agent within 30 days or 5 half-lives (whichever is longer) before the Screening Visit (compliance to be confirmed for the period between the Screening Visit and the Baseline Visit at the Baseline Visit).
see Link:

clinicaltrials.gov/NCT04629833

Study Test Center	PI / SC	Phone	E-Mail
UKSH Kiel Stem cell and immunotherapy	Dr. med. Natalie Schub Kerstin Eilts (SC)	0431 50022711 0431 500 22751	Natalie.Schub@uksh.de Kerstin.Eilts@uksh.de

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Myeloproliferative neoplasms (MPN)

continue...

Contact at UCC Hamburg
Dr. med. Philippe Schafhausen, Tel: 040 7410-57122

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A Phase 3, Randomized, Double-blind, Add-on Study Evaluating the Safety and Efficacy of Navtemadlin Plus Ruxolitinib Vs Placebo Plus Ruxolitinib in JAK Inhibitor-Naïve Patients with Myelofibrosis Who Have a Suboptimal Response to Ruxolitinib

Condition: Myelofibrosis, Post-PFMF, Post-ET Myelofibrosis, Primary Myeofibrosis
Primary Completion Date: 2026-12-13
Phase: III
Intervention/ Treatment: Drug: **Navtemadlin, Navtemadlin Placebo, Ruxolitinib**

Inclusion Criteria for Ruxolitinib Alone Period:
Confirmed diagnosis of PMF, post-PV MF, or post-ET MF, as assessed by the treating physician according to the World Health Organization (WHO) criteria / High, Intermediate-1, Intermediate-2 risk category International Prognosis System Score (IPSS) / Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 / JAK-inhibitor treatment naive
Exclusion Criteria for Ruxolitinib Alone Period:
Prior Splenectomy / Splenic irradiation within 3 months prior to the first dose / Prior BCL-XL, BET, MDM2, PI3K, PIM, or XPO1 inhibitors therapy or p53-directed therapy / Eligible for Bone Marrow Transplant Peripheral blood or bone marrow blast count ≥ 10 percent
Inclusion Criteria for Randomized Period:
PMF, post-PV MF, or post-ET MF that is TP53WT as assessed by central testing / ECOG performance status of 0 to 2 / Treatment with a stable dose of ruxolitinib / Suboptimal response to run-in ruxolitinib treatment
Exclusion Criteria for Randomized Period:
Elevated white blood cell count that doubles (or more) during ruxolitinib treatment and exceeds 50 × 10^9/L / Peripheral blood or bone marrow blast count ≥ 10 percent
see Link:

clinicaltrials.gov/NCT06479135

Study Test Center	PI / SC	Phone	E-Mail
UKE Medical Oncology	Dr. med. P. Schafhausen Petra Kühne (SC)	040-7410 57122 040-7410 54353	schafhausen@uke.de p.kuehne@uke.de

Universitäres Cancer Center HAMBURG
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Randomized, Open-label, Multicenter Phase 3 Study to Assess the Efficacy and Safety of GIVinostat Versus Hydroxyurea IN JAK2V617F-positive High-risk Polycythemia Vera Patients: the GIV-IN PV TRIAL

Condition: Polycythemia Vera
Primary Completion Date: 2026-07
Phase: III
Intervention/ Treatment: Drug: **Givinostat, Hydroxyurea**

Core Treatment Inclusion Criteria:
Patients must have been diagnosed with PV according to the 2016 WHO criteria before randomization / Patients must have JAK2V617F-positive disease / Patients with PV must meet the definition of HR for thrombosis (i.e., HR) within 3 years before screening as follows: / Age ≥ 60 years, and/or / Prior thrombosis. / Patients must be in need of treatment at screening, defined by the presence of at least **one of the following:** / HCT ≥ 45% or HCT < 45% with at least 1 phlebotomy performed in the 3 months before screening, **or** WBC count > 10 × 109/L, **or,** PLT count > 400 × 109/L. / Patients must have normalized HCT (i.e., HCT < 45%) at randomization
Extended Treatment Inclusion Criteria:
Patients must have completed the Week 48 visit of the DSC/08/2357/32 core treatment phase **and:** if the patient received givinostat, a complete hematological response (CHR) at Week 48 shall be achieved / if the patient received HU, did not achieve a CHR (see above for the definition) at Week 48
see Link:

clinicaltrials.gov/NCT06093672

Study Test Center	PI / SC	Phone	E-Mail
Oncoresearch Lerchenfeld	Frau R. Waldeck (Coordination)	040-22604650	r.waldeck@oncoresearch-lerchenfeld.de

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Mastocytosis

continue...

Contact at UCC Hamburg
Dr. med. Philippe Schafhausen, Tel: 040 7410-57122

Currently no study options

continue...

Hodgkin`s disease

continue...

Contact at UCC Hamburg
Prof. Dr- med. Judith Dierlamm, Tel.: 040 7410-53782

Currently no study options

continue...

Non-Hodgkin's lymphoma (NHL)

+

Waldenström's disease

continue...

Contact at UCC Hamburg
Prof. Dr- med. Judith Dierlamm, Tel.: 040 7410-53782

A Randomized, Open-label, Phase 3 Study of Acalabrutinib in Combination With Rituximab and Reduced Dose CHOP (R-miniCHOP) in OldEr Adults With Untreated Diffuse Large B-Cell Lymphoma

Condition: Large B-cell Lymphoma/ Diffuse Large B Cell Lymphoma
Primary Completion Date: 2028-04
Phase: III
Intervention/ Treatment: DRUG: **R-miniCHOP + Acalabrutinib/ R-miniCHOP**

Inclusion Criteria:
Informed consent / Ability to understand the purpose and risks of the study and capable of giving signed informed consent which includes: / Compliance with the requirements and restrictions listed in the informed consent form (ICF). / Authorization to use protected health information/data [in accordance with the General Data Protection Regulation (GDPR)]. / Provision of signed and dated, written ICF prior to any mandatory study specific procedures, sampling, and analyses / Willing and able to participate in all required evaluations and procedures in this study protocol, including swallowing capsules and tablets without difficulty. / Age/Sex / Men and women >80 years of age or >60 up to 80 years of age and ineligible for full dose R-CHOP according to investigator assessment*. / We recommend classifying patients aged 61-80 as full-dose R-CHOP ineligible if they fulfill one of the following criteria: ADL <5, IADL <6, CIRS-G ≥1 score = 3, or > 8 score = 2. / Male patients who are sexually active with women of childbearing potential (definitions see section 17.8) must agree to use highly effective forms of contraception with the addition of a barrier method (condom) during the study (see section 17.8.1) as well as to the restrictions mentioned in section 9.13. / Female patients of childbearing potential (definitions see 17.8) who are sexually active must agree to use highly effective forms of contraception while on the study as well as to the restrictions mentioned in section 9.13. / Disease characteristics: Histologically proven, previously untreated CD20+ diffuse large B-cell lymphoma (DLBCL) according to the 2017 WHO classification **including:** / diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) / primary cutaneous DLBCL leg type / intravascular large B-cell lymphoma / EBV+ DLBCL, NOS / HHV8+DLBCL, NOS / primary mediastinal (thymic) large B-cell lymphoma / B-cell lymphoma, with intermediate features between DLBCL and classical Hodgkin lymphoma / follicular lymphoma grade 3B / high-grade B-cell lymphoma, NOS / high-grade B-cell lymphoma, with MYC and BCL2 and/or BCL6 rearrangements / T-cell/histiocyte-rich large B-cell lymphoma / DLBCL associated with chronic inflammation / ALK+ large B-cell lymphoma / large B-cell lymphoma with IRF4 rearrangement Please note: patients in whom indolent lymphoma is diagnosed concurrently with the one of the above listed **diagnoses can also be included**. / Disease Stage I with bulk ≥7.5cm, II, III or IV according to Ann Arbor Classification Type of patient and clinical characteristics / Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2. An ECOG Score of 3 is acceptable only if this is directly attributable to lymphoma. / **Meet the following laboratory parameters**: / Absolute neutrophil count (ANC) ≥ 1500 cells/µl or platelet count ≥ 100.000/µl unless directly attributable to lymphoma. / Serum AST and ALT ≤3 x upper limit of normal (ULN) unless directly attributable to lymphoma. / Total bilirubin ≤1.5 x ULN, unless directly attributable to Gilbert's syndrome or lymphoma. / Estimated creatinine clearance of ≥30 mL/min, calculated by Cockcroft-Gault (using actual body weight) (if male, [140-Age] x Mass [kg] / [72 x creatinine mg/dL]; multiply by 0.85 if female), or serum creatinine ≤2.5 x ULN.
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT05820841

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
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Combining Loncastuximab Tesirine and Epcoritamab in Relapsed/Refractory Diffuse Large B-cell Lymphoma (DLBCL)

Condition: Aggressive Diffuse Large B-cell Lymphoma/ High-grade B-cell Lymphoma (HGBL)/ Follicular Lymphoma (FL) Grade 3B
Primary Completion Date: 2030-01-15
Phase: II
Intervention/ Treatment: DRUG: **Loncastuximab Tesirine and Epcoritamab**

Inclusion Criteria:
Subjects with histologically confirmed relapsed/refractory DLBCL based on pathology report (WHO 2022 criteria) / DLBCL (de novo or transformed) / High-grade B-cell lymphoma with MYC and BCL2 rearrangements / High-grade B-cell lymphoma, not otherwise specified (NOS) / Follicular lymphoma grade 3B / Diagnostic biopsy performed at the time of relapse/progressive disease no longer than 3 months before study entry must be available, with sufficient material for central review and complimentary scientific analyses. CD20 expression (or a high likelihood of CD20 expression) based on immunohistochemistry should be documented prior enrollment into the study. / Refractory disease is defined as no remission to the last therapy. Subjects intolerant to previous therapy are excluded. Two groups of patients are eligible: / Progressive disease (PD) or stable disease (SD) as best response to previous therapy. / Complete (CR) or partial response (PR) as the best response after previous therapy, with biopsy-proven relapse occurring < 6 months after end of treatment. / Relapsed disease is defined as subjects achieving complete or partial remission to previous therapy, followed by biopsy-proven relapse ≥6 months after treatment completion. Subjects with refractory and early relapsed (≤12 months) disease after first line anti-CD20-/anthracycline-containing therapy are eligible. Subjects with late relapsed (>12 months) disease after first line anti-CD20-/anthracycline-containing therapy can be enrolled in the study only if deemed ineligible to high dose chemotherapy (HDCT) followed by autologous stem cell transplantation (ASCT). Subjects relapsed/refractory to second line CAR-T cell therapy are eligible. / Subject must be 18 years or older. / Subject must be eligible to receive and in need of treatment initiation based on symptoms and/or disease burden, as assessed by the investigator. / Eastern Cooperative Oncology Group Performance (ECOG) status 0-2. / Subject must have one or more measurable disease sites defined as follows: / A positron emission tomography/computed tomography (PET/CT) scan demonstrating PET- positive lesion(s) AND At least one measurable nodal lesion (long axis > 1.5 cm and short axis > 1.0 cm) or ≥ one measurable extra-nodal lesion (long axis > 1.0 cm) on CT scan or MRI. / Ability to understand and willingness to sign written informed consent. Signed informed consent must be obtained before any study specific procedure. / Adequate baseline organ function tests collected no more than 7 days before starting study treatment: / Total bilirubin ≤ 1.5 times the upper limit of normal (ULN), except for patients with Gilbert syndrome, cholestasis due to hepatic hilum adenopathies or liver involvement, or biliary obstruction due to lymphoma, who may have a total bilirubin ≤ 3 times the ULN. / Alanine transaminase (ALT) and aspartate aminotransferase (AST) and gamma-glutamyl transferase (GGT) ≤ 2.5 times the ULN, or ≤ 5 times the ULN for patients with liver involvement by lymphoma. / Glomerular filtration rate (GFR) ≥ 45 mL/min/1.73 m² according to the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula. If not initially within target range, this evaluation may be repeated after at least 24 hours, either using the CKD-EPI formula or by 24-hour sampling. If the subsequent result is within the acceptable range, it may be used to fulfill the inclusion criteria. / Prothrombin time/international normalized ratio (INR)/activated partial thromboplastin time (aPTT) ≤ 1.5 times the ULN, unless the patient is receiving anticoagulation (although the INR should not exceed 4.0). / Platelet count ≥ 75,000/mm³ without transfusion in the prior 7 days. / Hemoglobin ≥ 8 g/dL. / Absolute neutrophil count ≥ 1,000/mm3 (off growth factors at least 72 hours). / Left ventricular ejection fraction > 45%. / more follow Link.
see Link:

clinicaltrials.gov/NCT07197307

Study Test Center	PI / SC	Phone	E-Mail
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Early Treatment Intensification in Patients With High Risk Mantle Cell Lymphoma Using CAR-T-cell Treatment After an Abbreviated Induction Therapy With Rituximab and Ibrutinib and 6 Months Ibrutinib Maintenance (Arm A) as Compared to Standard of Care Induction and Maintenance (Arm B)

Condition: Mantle Cell Lymphoma (MCL)
Primary Completion Date: 2031-06-15
Phase: II
Intervention/ Treatment: DRUG: **KTE-X19/ Ibrutinib**

Inclusion Criteria:
Histologically confirmed diagnosis of MCL according to WHO classification, with documentation of either overexpression of cyclin D1 or presence of t(11;14) / At least one High Risk MCL - feature as defined as I. MIPI-c high intermediate (HI) or high (H) risk (i.e. high risk MIPI irrespective of Ki-67 or intermediate risk MIPI and Ki-67>=30% (Ki-67 based on local pathology) and/or II. TP53-mutation and/or TP53-overexpression by immunohistochemistry (> 50% of lymphoma cells) / No prior treatment for MCL / Stage II-IV (Ann Arbor) / 18-75 years / At least 1 measurable lesion according to the Lugano Response Criteria (>1.5 cm nodal lesion or > 1cm extranodal lesion); in case of bone marrow infiltration only, bone marrow aspiration and biopsy is mandatory for all staging evaluations. / ECOG performance status ≤ 2 / **The following laboratory values at screening (unless discrepancies are related to MCL):** I. Absolute neutrophil count (ANC) ≥ 1000 cells/µL II. Platelets ≥75,000 cells/µL III. Creatinine <2 mg/dL or calculated creatinine clearance ≥60 mL/min IV. Transaminases (AST and ALT) < 2.5 x ULN V. Total bilirubin <= 2 x ULN unless other reason known (e.g. Gilbert-Meulengracht-Syndrome, or due to lymphoma involvement) / No evidence of CNS-disease / Written informed consent form according to ICH/EU GCP and national regulations, ability to follow study instructions and likely to attend and complete all required visits / Sexually active men and women of child-bearing potential must agree to use one of the highly effective contraceptive methods (combined oral contraceptives using two hormones, contraceptive implants, injectables, intrauterine devices, sterilized partner) together with one of the barrier methods (latex condoms, diaphragms, contraceptive caps) while on study; this should be maintained for 6 months after the last dose of KTE-X19 or for 3 months after last dose of Ibrutinib, whichever is longer / Negative serum or urine pregnancy test (Females of childbearing potential only, Females who have undergone surgical sterilization or who have been postmenopausal for at least 2 years are not considered to be of childbearing potential) / Willingness not to drive a motor vehicle for 8 weeks post CAR T cell treatment / Possibility to reach the site within 2 hours in case of toxicity / emergency
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT06482684

Study Test Center	PI / SC	Phone	E-Mail
UKE Medical Oncology	Prof. Dr. med. Francis Ayuketang Ayuk Natascha von Huenerbein (SC)	040 7410 – 55250 040 7410 – 23181	ayuketang@uke.de Na.von-Huenerbein@uke.de
UKSH Kiel Medical Clinic II	Prof. Dr. med. Christiane Pott Gunda Heydorn-Heistermann (SC)	0431 500 22516 0431 500 22561	Christiane.Pott@uksh.de Gunda.Heydorn-Heistermann@uksh.de

Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Phase II Trial to Assess the Efficacy of Low Radiation Dose of 20 Gy for the Treatment of Marginal Zone Lymphoma or Follicular Lymphoma Stage I-II Localized in the Stomach or the Duodenum

Condition: Follicular Lymphoma (Gastric or Duodenal)/ Marginal Zone Lymphoma (Gastric or Duodenal)
Primary Completion Date: N/A
Phase: II
Intervention/ Treatment: RADIATION: **Radiation Therapy**

Inclusion Criteria:
primary indolent gastric or duodenal lymphoma / pathology: marginal zone lymphoma (MZL) or follicular lymphoma (FL) / stage: clinical stage I or II (Ann Arbor classification) / H. pylori negative or antibiotic resistant lymphoma / IPI or FLIPI score low - high (0-4) / any size of tumor or affected lymph nodes / male or female with age ≥ 18 years / performance status ECOG 0 - 3 / written informed consent by the patient

Exclusion Criteria:
prior radiation treatment of the gastrointestinal lymphoma / stage: clinical stage III or IV (Ann Arbor classification)-unability to understand the informed consent or unwillingness to participate in the study / severe comorbidity or organ dysfunction contraindicating the use of RT (liver cirrhosis Child-Pugh C, chronic obstructive pulmonary disease GOLD 4, heart insufficiency NYHA IV, dialysis dependent renal insufficiency, uncontrolled epilepsy) / known seropositivity for HIV / acute hepatitis B or C infection / chronic inflammatory bowel disease / prior malignant disease (exclusion: basalioma, non-metastasized solid tumor in constant remission diagnosed >3 years ago) / pregnancy or breastfeeding / active substance abuse or severely compromised compliance

see Link:

clinicaltrials.gov/NCT04097067

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

Symphony-1: A Phase 1b/3 Double-Blind, Randomized, Active-Controlled, 3-Stage, Biomarker Adaptive Study Of Tazemetostat Or Placebo In Combination With Lenalidomide Plus Rituximab In Subjects With Relapsed/Refractory Follicular Lymphoma

Condition: Follicular Lymphoma/ Follicular Lymphoma relapsed/ refractory
Primary Completion Date: 2026-03-01
Phase: III
Intervention/ Treatment: DRUG: **Tazemetostat/ Placebo oral tablet**_COMBINATION PRODUKT: **Lenalidomide/ Rituximab**

Inclusion Criteria:

Have voluntarily agreed to provide written informed consent and demonstrated willingness and ability to comply with all aspects of the protocol. / Males or females are ≥18 years of age at the time of providing voluntary written informed consent. / Life expectancy ≥3 months before enrollment. / **Meet requirement for hepatitis and human immunodeficiency virus (HIV) infection as follows:** Negative serologic or polymerase chain reaction (PCR) test results for acute or chronic hepatitis B virus (HBV) infection Note: Participants whose HBV infection status could not be determined by serologic test results have to be negative for HBV-DNA by PCR to be eligible for study participation. Participants seropositive for HBV with undetectable HBV DNA by PCR are permitted with appropriate antiviral prophylaxis. / Negative test results for hepatitis C virus (HCV) Note: Participants who are positive for HCV antibody must be negative for HCV RNA by PCR to be eligible for study participation / If HIV positive, HIV infection is controlled / Have histologically confirmed FL, Grades 1 to 3A. / Must have been previously treated with at least 1 prior systemic chemotherapy, immunotherapy, or chemoimmunotherapy: / a. Systemic therapy includes treatments such as: i. Rituximab monotherapy / ii. Chemotherapy given with or without rituximab / iii. Radioimmunoconjugates such as 90Y-ibritumomab tiuxetan and 131I-tositumomab. / b. **Systemic therapy does not include, for example**: i. Local involved field radiotherapy for limited-stage disease / ii. Helicobacter pylori eradication / c. Prior investigational therapies will be allowed provided the subject has received at least 1 prior systemic therapy as discussed in Inclusion Criterion #6a. / d. Prior autologous/allogeneic hematopoietic stem cell transplant (HSCT) will be allowed. / e. Prior chimeric antigen receptor T-cell therapy (CAR T) will be allowed. / Must have documented relapsed, refractory, or PD after treatment with systemic therapy (refractory defined as less than PR or disease progression <6 months after last dose). / Have measurable disease as defined by the Lugano Classification (Cheson, 2014; Appendix 5). / Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2. / Within 7 days prior to randomization, all clinically significant toxicity related to a prior anticancer treatment (ie, chemotherapy, immunotherapy, and/or radiotherapy must have either resolved to Grade 1 per NCI CTCAE Version 5.0 OR are clinically stable and no longer clinically significant. / Have provided sufficient tumor tissue block or unstained slides for EZH2 mutation testing in all subjects to allow for stratification / a. If EZH2 mutation status is known from site-specific testing, subjects can be enrolled. Tumor tissue will be required for confirmatory testing of EZH2 status at study-specific laboratories. If the archival tumor sample was collected more than 24 months prior to the anticipated administration of the first dose (cycle 1 day 1), then a fresh biopsy must be provided. Fresh tumor biopsy is appropriate except for procedures deemed to result in unacceptable risk because of the anatomical location including brain, lung/mediastinum, pancreas, or endoscopic procedures extending beyond the esophagus, stomach, or bowel. Archival tumor biopsy sections mounted on slides are also acceptable. / NOTE: Confirmatory testing will also be performed for Stage 1, if local EZH2 testing is conducted, unless there is insufficient tumor tissue to perform testing after discussion with the Sponsor's or Designee Medical Monitor. / Time between prior anticancer therapy and first dose of tazemetostat as follows: / Cytotoxic chemotherapy - At least 21 days. / Noncytotoxic chemotherapy (eg, small molecule inhibitor) - At least 14 days. / Nitrosoureas - At least 6 weeks. / Monoclonal and/or bispecific antibodies or CAR T - At least 28 days. / Radiotherapy - At least 6 weeks from prior radioisotope therapy; at least 12 weeks from 50% pelvic or total body irradiation. / Adequate renal function defined as calculated creatinine clearance ≥30 mL/minute per the Cockcroft and Gault formula. / Adequate bone marrow function: / a. Absolute neutrophil count (ANC) ≥1000/mm3 (≥1.0 × 10^9/L) if no lymphoma infiltration of bone marrow OR ANC ≥750/mm3 (≥75 × 10^9/L) with bone marrow infiltration / Without growth factor support (filgrastim or pegfilgrastim) for at least 14 days. / b. Platelets ≥75,000/mm3 (≥75 × 10^9/L) / Evaluated at least 7 days after last platelet transfusion. / c. Hemoglobin ≥9.0 g/dL / May receive transfusion / Adequate liver function: / Total bilirubin ≤1.5 × the upper limit of normal (ULN) except for unconjugated hyperbilirubinemia of Gilbert's syndrome. / Alkaline phosphatase (ALP) (in the absence of bone disease), alanine aminotransferase (ALT), and aspartate aminotransferase (AST) ≤3 × ULN (≤5 × ULN if subject has liver infiltration). / International normalized ratio (INR) ≤1.5 × ULN and activated partial thromboplastin time (aPTT) ≤1.5 × ULN (unless on warfarin, then INR ≤3.0). In subjects with thromboembolism risk, prophylactic anticoagulation, or antiplatelet therapy at investigator discretion is recommended. / Females of childbearing potential (FCBP) must have a negative urine or serum pregnancy tests (beta-human chorionic gonadotropin [β-hCG] tests with a minimum sensitivity of 25 mIU/mL or equivalent units of β-hCG) at screening within 10 to 14 days prior to first dose of study drug. The subject may not receive study drug until the study doctor has verified that the results of pregnancy tests are negative. All females will be considered to be of childbearing potential unless they are naturally postmenopausal (at least 24 months consecutively amenorrhoeic [amenorrhea following cancer therapy does not rule out childbearing potential] and without other known or suspected cause) or have been sterilized surgically (ie, total hysterectomy and/or bilateral oophorectomy, with surgery completed at least 1 month before dosing). / Females of childbearing potential (FCBP) enrolled must either practice complete abstinence or agree to use two reliable methods of contraception simultaneously. This includes ONE highly effective method of contraception and ONE additional effective contraceptive method. Contraception must begin at least 28 days prior to first dose of study drug, continue during study treatment (including during dose interruptions), and for 12 months after study drug discontinuation. Female subjects must also refrain from breastfeeding for 12 months following last dose of study drug. If the below contraception methods are not appropriate for the FCBP, she must be referred to a qualified contraception provider to determine the medically effective contraception method appropriate for the subject. The following are examples of highly effective and additional effective methods of contraception:

Exclusion Criteria:

see Link:

clinicaltrials.gov/NCT04224493

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG

Universitätsklinikum Hamburg-Eppendorf

A Phase 1/2, Open-Label, Dose-Escalation and -Expansion Study of the Bruton Tyrosine Kinase Targeted Protein Degrader BGB-16673 in Patients With B-Cell Malignancies

Condition: B-cell Malignancy/ Marginal Zone Lymphoma/ Follicular Lymphoma/ Non-Hodgkin Lymphoma/ Waldenström Macroglobulinemia/ Chronic Lymphocytic Leukemia/ Small Lymphocytic Lymphoma/ Mantle Cell Lymphoma/ Diffuse Large B Cell Lymphoma

Primary Completion Date: 2026-11

Phase: I/II

Intervention/ Treatment: DRUG: **BGB-16673**

Inclusion Criteria:

Confirmed diagnosis (per World Health Organization (WHO) guidelines, unless otherwise noted) of one of the following: Marginal Zone Lymphoma (MZL), R/R follicular lymphoma (FL), mantle cell lymphoma (MCL), chronic lymphocytic leukemia and small lymphocytic lymphoma (CLL/SLL), Waldenström macroglobulinemia (WM), R/R diffuse large B-cell lymphoma (DLBCL), or Richter's transformation to DLBCL. / Participants who have previously received a covalently-binding Bruton´s tyrosine kinase (BTK) inhibitor (BTKi) in any line of therapy must have received treatment with the BTK inhibitor for ≥ 8 weeks (unless reason for discontinuation is intolerance). / For dose-finding and dose-expansion, participants who had previously received a covalently-binding BTK inhibitor as monotherapy or in combination with other anticancer agents are eligible for the study if they meet any of the following criteria: discontinued the previous BTK inhibitor due to disease progression, experienced disease progression after completing treatment with a BTK inhibitor or discontinued the BTK inhibitor due to toxicity or intolerance. / Measurable disease by radiographic assessment or serum IgM level (WM only) / Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 2 / Participants enrolling in the dose finding phase of the study may be previously treated with a BTKi or may be naïve to BTKi therapy depending on the diagnosis and country of enrollment; participants with MCL enrolling in the expansion cohorts (Phase 2) must have been treated with a BTKi in a prior line of therapy; CLL/SLL participants, in addition to being treated with a BTKi in a prior line of therapy, must also have received a Bcl-2 inhibitor in a prior line of therapy as well (Phase 2).

Exclusion Criteria:

Prior malignancy (other than the disease under study) within the past 2 years, except in situ malignancies that have been curatively resected, localized breast cancer treated with curative intent with no evidence of breast active disease for more than 3 years and receiving adjuvant hormonal therapy, localized Gleason score ≤ 6 prostate cancer undergoing observation or treatment with androgen depravation, or any other cancer treated with curative intent, not on adjuvant treatment, and in the opinion of the investigator is unlikely to recur. /Requires ongoing systemic treatment for any other malignancy /Requires ongoing systemic (defined as ≥ 10 mg/day of prednisone or equivalent) corticosteroid treatment. /Current or history of central nervous system involvement including the brain, spinal cord, leptomeninges, and cerebrospinal fluid (as documented by imaging, cytology, or biopsy) by B-cell malignancy, regardless of whether participants had received treatment for central nervous system disease /Known active plasma cell neoplasm, prolymphocytic leukemia, T-cell lymphoma, Burkitt lymphoma, acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma, Castleman disease, post-transplant lymphoproliferative disorders, hairy cell leukemia, germinal center B-cell (GCB), DLBCL, EBV+ DLBCL NOS, primary DLBCL of the central nervous system (CNS), primary cutaneous DLBCL - leg type, DLBCL associated with chronic inflammation, primary mediastinal (thymic) large B-cell lymphoma, intravascular large B-cell lymphoma, ALK+ large B-cell lymphoma, primary effusion lymphoma, high-grade B-cell lymphoma with MYC and BCL2 and/or BCL6 rearrangements, high-grade B-cell lymphoma - NOS, B-cell lymphoma unclassifiable with features intermediate between DLBCL and classical Hodgkin lymphoma, or history of or currently suspected transformation of an indolent lymphoma to an aggressive histology (except for participants with Richter Transformation to DLBCL are eligible for Part 1a, 1c, or Phase 2 and participants with history of follicular lymphoma transforming to non-GCB DLBCL who are eligible for Part 1a, 1c, or Phase 2).

Note: Other protocol defined Inclusion/Exclusion criteria may apply.

see Link

clinicaltrials.gov/NCT05006716

Study Test Center	PI / SC	Phone	E-Mail
UKSH Lübeck Hematology and Oncology	Prof. Dr. med. Nikolas von Bubnoff Emilia Prieß	0451 500 44151 0451 500 44355	NikolasChristianCornelius.vonBubnoff@uksh.de emilia.priess@uksh.de

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Universitätsklinikum Hamburg-Eppendorf

First-in-Human Study to Evaluate the Safety, Pharmacokinetics, and Preliminary Efficacy of the BTK Degrader, ABBV-101, in Participants With B-cell Malignancies

Condition: Hematologic Cancer
Primary Completion Date: 2031-03
Phase: I
Intervention/ Treatment: DRUG: **ABBV-101**

Inclusion Criteria:
For Dose Escalation (Part 1) only: Participants with documented diagnosis for one of the following 3L+ B-cell malignancies, from one of the following WHO-defined histologies (Swerdlow et al 2016): Chronic lymphocytic leukemia (CLL) / Small lymphocytic lymphoma (SLL) / Chimeric antigen receptor T-cells (CAR-T)/hematopoietic cell transplant (HCT) relapsed/refractory (R/R) or ineligible diffuse large b-cell lymphoma (DLBCL) from the following histologies: DLBCL not otherwise specified (NOS) (germinal center B cell [GCB] and non-GCB DLBCL), T-cell/histiocyte-rich large B-cell lymphoma, primary mediastinal (thymic) large B-cell lymphoma, intravascular large B-cell lymphoma, anaplastic lymphoma kinase positive (ALK+) large B-cell lymphoma, high-grade B-cell lymphoma with MYC and BCL2 and/or BCL6 rearrangements, and high-grade B-cell lymphoma NOS. / Mantle cell lymphoma (MCL) / Follicular lymphoma [FL] (grades 1-3b) / Marginal zone lymphoma [MZL] (splenic, extranodal, and nodal) / Waldenström macroglobulinemia (WM) / Transformed indolent non-Hodgkin's lymphoma (iNHL) /
•For Dose Expansion (Part 2) only: Participants with documented diagnosis of CLL who are 3L+ including those with Bruton's tyrosine kinase (BTK) mutations or CAR-T/HCT R/R or ineligible non-GCB DLBCL who are 3L+ with histology based on criteria established by the World Health Organization (WHO). / Has an Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) of 0, 1, or 2. For EU only: Participant has an ECOG PS of 0 or 1. / Participant has a life expectancy >= 12 weeks. / Prior Bruton's tyrosine kinase inhibitor (BTKi) is allowed. / Adequate hematologic, renal, and hepatic function per the protocol. / Participants with prior central nervous system (CNS) disease that have been effectively treated may be eligible.
Exclusion Criteria:
Previously treated with a Bruton's tyrosine kinase (BTK) degrader. / Known active CNS disease, or primary CNS lymphoma. / Uncontrolled active systemic infection, or active cytomegalovirus infection, known history of human immunodeficiency virus (HIV), active hepatitis B or C infection or less than 12 weeks since achieving undetectable viral load in cases of prior active hepatitis C.
see Link

clinicaltrials.gov/NCT05753501

Study Test Center	PI / SC	Phone	E-Mail
UKE Medical Oncology	Dr. med. Franziska Westendorf Alexandra Pfeffer(SC)	0152-228 277 89 040-7410 58073	Franziska.Westendorf@uke.de A.Pfeffer@uke.de

Venetoclax in combination with the BTK inhibitor Ibrutinib and Rituximab or conventional chemotherapy (Bendamustine) and Ibrutinib and Rituximab in patients with treatment naive Mantle Cell Lymphoma not eligible for high dose therapy.

Condition: Mantle Cell Lymphoma (MCL)
Primary Completion Date: /
Phase: II
Intervention/ Treatment: DRUG: **Venetoclax/ Ibrutinib/ Rituximab/ Bendamustine**

Inclusion Criteria:
Histologically confirmed diagnosis of MCL according to WHO classification / - previously untreated stage II-IV (Ann Arbor) / - ≥ 60 years and not suitable for autologous SCT / - At least 1 measurable lesion; in case of bone marrow infiltration only, bone marrow aspiration and biopsy is mandatory for all staging evaluations. / - ECOG performance status ≤ 2 / **The following laboratory values at screening (unless related to MCL):** - Absolute neutrophil count (ANC) ≥ 1000 cells/µL / - Platelets ≥75.000 cells/µL / - Transaminases (AST and ALT) ≤3 x ULN / - Total bilirubin ≤ 2 x ULN unless other reason known (Gilbert-Meulengracht-Syndrome) / - Creatinine ≤ 2 mg/dL or eGFR ≥ 50 mL/min / - Written informed consent form according to ICH/EU GCP and national regulations /
- Sexually active men with female partners of child-bearing potential potential must agree to use highly effective contraceptives

Exclusion Criteria:
Major surgery within 4 weeks prior to first dose / - Requires anticoagulation with warfarin or equivalent vitamin K antagonists (e.g. phenprocoumon) / - History of stroke or intracranial hemorrhage within 6 months prior to first dose / - Treatment with strong or moderate CYP3A4/5 inhibitors/inducers within 7 days before first dose and during Venetoclax and Ibrutinib intake / - Any life-threatening illness, medical condition, or organ system dysfunction which, in the investigator's opinion, could compromise the subject's safety, interfere with the absorption or metabolism of Ibrutinib capsules, or put the study outcomes at undue risk / - Vaccinated with live, attenuated vaccines within 4 weeks prior to first dose / - Known CNS involvement of MCL / - Known bleeding disorder (e.g. von Willebrand disease; hemophilia) / Serious concomitant disease interfering with a regular therapy according to the study protocol: / - Cardiac (Clinically significant cardiovascular disease such as uncontrolled or symptomatic arrhythmias, congestive heart failure, or myocardial infarction within 6 months of Screening, or any Class 3 (moderate) or Class 4 (severe) cardiac disease as defined by the New York Heart Association Functional Classification or LVEF below LLN) / - Pulmonary (e.g. chronic lung disease with hypoxemia, e.g. DLCO ≤ 65% or FEV1 ≤ 65%) / - Endocrinological (e.g. severe, not sufficiently controlled diabetes mellitus) / - Patients with unresolved hepatitis B or C infection or known HIV positive infection (mandatory test) / Concomitant or previous malignancies within the last 3 years other than basal cell skin cancer, Prostate cancer in remission with PSA within normal range or in situ uterine cervix cancer.
see Link:

clinicaltrialsregister.eu/2020-002935-30

Study Test Center	PI / SC	Phone	E-Mail
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A Phase 3 Randomized Double-Blind Multicenter Study of Sonrotoclax Plus Zanubrutinib Versus Placebo Plus Zanubrutinib in Patients With Relapsed/Refractory Mantle Cell Lymphoma

Condition: Mantle Cell Lymphoma, B Cell Lymphoma
Primary Completion Date: 2029-03-31
Phase: III
Intervention/ Treatment: DRUG: **Sonrotoclax/ Zanubrutinib/ Placebo**

Inclusion Criteria:
Histologically confirmed diagnosis of MCL based on the World Health Organization 2022 classification of Haematolymphoid Tumors (WHO-HAEM5), or based on International Consensus Classification (ICC) / Received 1 to 5 prior lines of systemic therapy including an anti-CD20 monoclonal antibody (mAb)-based immunotherapy or chemoimmunotherapy and requiring treatment in the opinion of the investigator / Relapsed or refractory disease after the last line of therapy / Measurable disease defined as ≥ 1 nodal lesion that is > 1.5 cm in longest diameter, or ≥ 1 extranodal lesion that is > 1 cm in longest diameter / Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 2 / Adequate organ function

Exclusion Criteria:
Prior therapy with B-cell lymphoma-2 inhibitor / Prior therapy with covalent or non-covalent Bruton tyrosine kinase inhibitor (BTKi) unless the participant was intolerant of non-zanubrutinib covalent or non-covalent BTKi / Prior autologous stem cell transplantation or chimeric antigen receptor T-cell therapy within 3 months before first dose of study drug / Prior allogeneic stem cell transplant within 6 months of the first dose of the study drug / Known central nervous system involvement by lymphoma / Clinically significant cardiovascular disease / History of stroke or intracranial hemorrhage within 6 months before first dose of study drug / Note: Other protocol defined Inclusion/Exclusion criteria may apply.

see Link:

clinicaltrials.gov/NCT06742996

Study Test Center	PI / SC	Phone	E-Mail
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Multiple Myeloma

continue...

Contact at UCC Hamburg
Prof. Dr. med. Katja Weisel, Tel.: 040 7410-58787

An Open-label, Randomized, Phase 3 Study of Linvoseltamab (REGN5458; Anti- BCMA x Anti-CD3 Bispecific Antibody) Versus the Combination of Elotuzumab, Pomalidomide, and Dexamethasone (EPd), in Patients With Relapsed/Refractory Multiple Myeloma

Condition: Relapsed Refractory Multiple Myeloma (RRMM)
Primary Completion Date: 2032-12-26
Phase: III
Intervention/ Treatment: DRUG: **Linvoseltamab/ Elotuzumab/ Pomalidomide/ Dexamethasone**

Inclusion Criteria:
Age 18 years or older (or legal adult age in the country) at the time of the screening visit. / Eastern Cooperative Oncology Group (ECOG) performance status ≤1. Patients with ECOG 2 solely due to local symptoms of myeloma (eg. pain) may be allowed after discussion with the Medical Monitor. / Received at least 1 and no more than 4 prior lines of anti-neoplastic MM therapies, including lenalidomide and a proteasome inhibitor and demonstrated disease progression on or after the last therapy as defined by the 2016 IMWG criteria. Participants who have received only 1 line of prior line of antimyeloma therapy must be lenalidomide refractory, as described in the protocol. / **Note:** Participants in Israel also must have previously received a CD38 antibody. Participants in the EU and the UK must have previously received 2 to 4 prior lines of therapy, including a CD38 antibody. / Patients must have measurable disease for response assessment as per the 2016 IMWG response assessment criteria, as described in the protocol / Adequate hematologic, hepatic, renal and cardiac function, as well as evidence of adequate bone marrow reserves / Life expectancy of at least 6 months

Exclusion Criteria:
Diagnosis of plasma cell leukemia, amyloidosis, Waldenström macroglobulinemia, or POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes). / Prior treatment with elotuzumab and/or pomalidomide / Participants with known MM brain lesions or meningeal involvement / Treatment with any systemic anti-cancer therapy within 5 half-lives or within 28 days before first administration of study drug, whichever is shorter / History of allogeneic stem cell transplantation within 6 months, or autologous stem cell transplantation within 12 weeks of the start of study treatment. Participants who have received an allogeneic transplant must be off all immunosuppressive medications for 6 weeks without signs of graft-versus-host disease. Steroids at doses equivalent to suppletion doses may be acceptable. / Prior treatment with B-cell maturation antigen (BCMA) directed immunotherapies Note: BCMA antibody-drug conjugates are allowed. / History of progressive multifocal leukoencephalopathy (PML), known or suspected PML, or history of a neurocognitive condition or central nervous system (CNS) movement disorder. / Any infection requiring hospitalization or treatment with IV anti-infectives within 2 weeks of first administration of study drug / Uncontrolled infection with human immunodeficiency virus (HIV), hepatitis B virus (HBV) or hepatitis C virus (HCV); or another uncontrolled infection, as defined in the protocol. / NOTE: Other protocol defined inclusion/exclusion criteria apply
see Link:

clinicaltrials.gov/NCT05730036

Study Test Center	PI / SC	Phone	E-Mail
UKE Medical Oncology	Prof. Dr. med. Katja Weisel Sarah Krug (Studienzentrale)	040-7410 58787 040-7410 59879	k.weisel@uke.de s.krug@uke.de
UKSH Lübeck Hematology and Oncology	Emilia Prieß (SC)	0451 500 44355	emilia.priess@uksh.de

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A multicenter, open-label Phase 1b/2a study to determine the recommended dose and dosing schedule and to evaluate the safety and preliminary efficacy of mezigdomide in combination with elranatamab in participants with relapsed and/or refractory multiple myeloma.

Condition: Multiple Myeloma
Primary Completion Date: 2027-05-31
Phase: I/II
Intervention/ Treatment: DRUG: **Elranatamab/ Mezigdomide/ Dexamethasone**

Inclusion Criteria:
Age ≥18 with history of relapsed and refractory multiple myeloma (RRMM) treated with 2 to 4 prior lines of anti-myeloma therapy (Phase 1) or 1 to 3 prior lines of anti-myeloma therapy (Phase 2). / Measurable MM by local laboratory. / Eastern Cooperative Oncology Group performance status (ECOG PS) of 0 to 1. / Adherence to contraception requirements.

Exclusion Criteria:
Prior treatment with mezigdomide. / Prior treatment with T cell engaging or T cell engager (TCE). / Prior treatment with B cell-maturation antigen (BCMA)-targeting therapy, with the exception of participants who have received autologous BCMA-targeted CART-cell therapy> 6 months from the start of study therapy / Other protocol-defined Inclusion/Exclusion criteria apply.

see Link:

clinicaltrials.gov/NCT06988488

Study Test Center	PI / SC	Phone	E-Mail
UKE Medical Oncology	Prof. Dr. med. Katja Weisel Sarah Krug (Studienzentrale)	040-7410 58787 040-7410 59879	k.weisel@uke.de s.krug@uke.de

Phase 2 Study Applying Innovative Minimal Residual Disease (MRD) Techniques for Participants With Previously Untreated Multiple Myeloma Treated With D-VRd Prior To and After High-dose Therapy Followed by Autologous Stem Cell Transplantation (ASCT)

Condition: Multiple Myeloma
Primary Completion Date: 2024-12
Phase: III
Intervention/ Treatment: DRUG: **Daratumumab/ Bortezomib/ Lenalidomide/ Dexamethasone**

Inclusion Criteria:
18 to 70 years of age, inclusive. / Must have a new diagnosis of MM as per IMWG criteria. / Measurable disease / Newly diagnosed and treatment-naïve participants for whom high-dose therapy and autologous stem cell transplantation is part of the intended treatment plan. / Eastern Cooperative Oncology Group (ECOG) performance status score of 0, 1, or 2. / Clinical laboratory values meeting the required criteria during screening and ≤3 days prior to receiving first study treatment dose. / Adequate bone marrow function. / Adequate liver function. / Adequate renal function. / A female of childbearing potential (FOCBP) must have two negative serum or urine pregnancy tests at screening including within 24 hours of the start of study treatment. / Willing to practicing at least 1 highly effective method of contraception starting 4 weeks prior to start of study treatment, while receiving study treatment including during any dose interruptions, and for at least 3 months after the last dose of any component of the study treatment.

Exclusion Criteria:
Prior or current systemic therapy or ASCT for any plasma cell dyscrasia, with the exception of emergency use of a short course (equivalent of dexamethasone 40 mg/day for a maximum 4 days) of corticosteroids before treatment. / History of allogenic stem cell transplantation or prior organ transplant requiring immunosuppressive therapy. / Peripheral neuropathy or neuropathic pain Grade 2 or higher, as defined by the National cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 5. / Myelodysplastic syndrome or any malignancy within 24 months of signing consent. The only exceptions are malignancies treated within the last 24 months that are considered completely cured. / Plasmapheresis ≤28 days of approval. / Radiation therapy for treatment of plasmacytoma ≤14 days of approval of enrollment. / Forced Expiratory Volume in 1 second (FEV1) <50% of predicted normal. / Concurrent medical or psychiatric condition or disease. / Myocardial infarction ≤6 months of enrollment, or an unstable or uncontrolled disease/condition related to or affecting cardiac function. / Uncontrolled cardiac arrhythmia or clinically significant electrocardiogram (ECG) abnormalities. / Allergy, hypersensitivity, or intolerance to boron or mannitol, corticosteroids, monoclonal antibodies or human proteins, or the excipients of daratumumab, lenalidomide, bortezomib or dexamethasone. Pregnant or breast-feeding females
see Link:

https://clinicaltrials.gov/NCT06189833

Study Test Center	PI / SC	Phone	E-Mail
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Phase 3 Study of Teclistamab in Combination With Lenalidomide and Teclistamab Alone Versus Lenalidomide Alone in Participants With Newly Diagnosed Multiple Myeloma as Maintenance Therapy Following Autologous Stem Cell Transplantation

Condition: Multiple Myeloma
Primary Completion Date: 2027-02-15
Phase: III
Intervention/ Treatment: DRUG: **Teclistamab/ Daratumumab/ Dexamethasone/ Lenalidomide/ Bortezomib/ Talquetamab**

Inclusion Criteria:
18 years of age to 70 years of age, inclusive / Have an ECOG performance status score of 0 to 2 at screening / Have clinical laboratory values meeting prespecified criteria during the Screening Phase. / Participants in Arms A, A1, B, D, E, E1, F and F1 must also satisfy all of the following criteria to be enrolled in the study: / 1. Documented Multiple Myeloma requiring treatment as defined by the criteria below: Multiple Myeloma diagnosis according to the IMWG diagnostic criteria / Measurable disease at screening as defined by any of the following: Serum M-protein level ≥1.0 g/dL or Urine M-protein level ≥200 mg/24 hours or Serum immunoglobulin free light chain level ≥10 mg/dL and abnormal serum free light chain ratio / 2. Newly diagnosed participants for whom HDT and ASCT is part of the intended treatment plan (except Arm D participants). / Participants Arm C and C2 must also satisfy all of the following criteria: Newly diagnosed Multiple Myeloma according to IMWG criteria. / Must have received 4 to 6 cycles of 3 or 4 drug-induction therapy that includes a proteasome inhibitor and/or an IMiD with or without anti-CD38 monoclonal antibody and a single or tandem ASCT. Post-ASCT consolidation is permitted for up to 2 cycles as long as the total number of induction plus consolidation cycles does not exceed 6. / 3 Must have received only one line of therapy and achieved at least a PR as per IMWG 2016 without evidence of progression at the time of enrollment. / 4. Must have received HDT and ASCT within 12 months of the start of induction therapy and be within 6 months of the last ASCT (7 months for participants who received consolidation) at the time of enrollment.
see Link:

clinicaltrials.gov/NCT05695508

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Phase 3, Randomized, Open-label Study of Belantamab Mafodotin Administered in Combination With Lenalidomide and Dexamethasone (BRd) Versus Daratumumab, Lenalidomide, and Dexamethasone (DRd) in Participants With Newly Diagnosed Multiple Myeloma Who Are Ineligible for Autologous Stem Cell Transplantation (TI-NDMM)

Condition: Multiple Myeloma, Newly Diagnosed Multiple Myeloma
Primary Completion Date: 2033-12-23
Phase: III
Intervention/ Treatment: DRUG: **Belantamab mafodotin/ Lenalidomide/ Dexamethasone/ Daratumumab**

Inclusion Criteria:
Is at least 18 or the legal age of consent in the jurisdiction in which the study is taking place, at the time of signing the informed consent. / Capable of giving signed informed consent, which includes compliance with the requirements and restrictions listed in the informed consent form and in the protocol. / NDMM with a requirement for treatment as documented per IMWG criteria. / **Must have at least 1 aspect of measurable disease, as assessed by the central laboratory, defined as 1 of the following:** Urine M-protein excretion ≥200 mg/24 hours (≥0.2 g/24 hours) **And/or** Serum M-protein concentration ≥0.5 g/dL (≥5.0 g/L) **And/or** Serum free light-chain (FLC) assay: involved FLC level ≥10 mg/dL (≥100 mg/L) and an abnormal serum FLC ratio (<0.26 or >1.65). / **Newly diagnosed and not considered candidate for high-dose chemotherapy with autologous stem cell transplant (ASCT) due to any of the following:** ≥70 years of age, **OR** Age 18 to 69 years with presence of comorbid condition(s) likely to have a negative impact on tolerability of high-dose chemotherapy with ASCT, (or for whom national guidelines do not permit transplant due to a cut-off age below 70 years), **OR** Who refuse high-dose chemotherapy with ASCT as an initial treatment. / Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2. / Adequate organ system function as defined by the laboratory assessments. / **Male participants:** Contraceptive use by men should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies. / Male participants are eligible to participate if they agree to the following during the Treatment Period and for at least 6 months after the last dose of study intervention to allow for clearance of any altered sperm: / Refrain from donating fresh unwashed semen / **PLUS either:** Be abstinent from heterosexual intercourse as their preferred and usual lifestyle (abstinent on a long term and persistent basis) and agree to remain abstinent. **OR** Must agree to use contraception/barrier as detailed below / Agree to use a male condom, even if they have undergone a successful vasectomy, and female partner to use an additional highly effective contraceptive method with a failure rate of <1% per year when having sexual intercourse with a woman of childbearing potential (WOCBP) who is not currently pregnant. Male participants should also use a condom when having sexual intercourse with pregnant females. / **Female participants:** Contraceptive use by women should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies. / A female participant is eligible to participate if she is not pregnant or breastfeeding, and at least 1 of the following conditions applies: / Is not a WOCBP **OR** Is a WOCBP and using a contraceptive method that is highly effective (with a failure rate of <1% per year), preferably with low user dependency during the Treatment Period and for 4 months after the last dose of study intervention and agrees not to donate eggs (ova, oocytes) for the purpose of reproduction during this period. The investigator should evaluate the effectiveness of the contraceptive method in relationship to the first dose of study intervention. / A WOCBP must have 2 negative highly sensitive serum pregnancy tests before starting treatment, the first may be performed within 14 days from C1D1, the second within 24 hours before the first dose of study intervention. / Should pregnancy occur in a female on treatment or the female partner of a male on treatment, treatment must be stopped, and it is advised to seek advice from a physician specialized or experienced in teratology.

Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT06679101

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A Phase 1/2a, First-in-human Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of HDP-101 in Patients With Plasma Cell Disorders Including Multiple Myeloma

Condition: Multiple Myeloma, Plasma Cell Disorder
Primary Completion Date: 2026-05
Phase: I/II
Intervention/ Treatment: DRUG: **HDP-101**

Inclusion Criteria:
Male or female aged ≥18 years. / Life expectancy >12 weeks. / Eastern Cooperative Oncology Group Performance Status (PS) of 0 to 2. / A confirmed diagnosis of active MM according to the diagnostic criteria established by the International Myeloma Working Group (IMWG). / Must have undergone SCT or is considered transplant ineligible. / Must have undergone prior treatments with antimyeloma therapy which must have included an immunomodulatory drug, proteasome inhibitor, and anti-CD38 treatment, alone or in combination. In addition, the patient should either refractory or intolerant to any established standard of care therapy providing a meaningful clinical benefit for the patient assessed by the Investigator. / Measurable disease as per IMWG criteria. / Adequate organ system function as defined in protocol.

Exclusion Criteria:
For patient entering the Phase 2a part only: Prior treatment with any approved or experimental BCMA-targeting modalities are not allowed. / Known central nervous system involvement. / Plasma cell leukemia. / History of congestive heart failure. / Autologous or allogenic SCT within 12 weeks before the first infusion or is planning for autologous SCT. / Symptomatic graft versus host disease post allogenic hemopoietic cell transplant within 12 months prior to the first study treatment infusion. / Radiotherapy within 21 days prior to the first study treatment infusion. / History of any other malignancy known to be active. / Known human immunodeficiency virus infection.
•Patients with active infection requiring systemic anti-infective. / Patients with positive test results for hepatitis B surface antigen or Hepatitis B core antigen. / Patients with positive test results for hepatitis C virus (HCV) infection. / Current active liver or biliary disease.

see Link:

clinicaltrials.gov/NCT04879043

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Phase 1-2 UMBRELLA Trial Evaluating Isatuximab With or Without Dexamethasone in Combination With Novel Agents Compared to Isatuximab With Pomalidomide and Dexamethasone in Relapsed or Refractory Multiple Myeloma (RRMM) - Master Protocol

Condition: Plasma Cell Myeloma Refractory
Primary Completion Date: 2028-04-20
Phase: I/II
Intervention/ Treatment: DRUG: **Isatuximab/ Dexamethasone/ Pomalidomide/ Belantamab mafodotin/ Pegenzileukin/ SAR439459/ Belumosudil/ Evorpacept**

Inclusion Criteria:
Participant must be 18 years of age inclusive or older. / Eastern Cooperative Oncology Group (ECOG) performance status 0-1. / Participants with relapsed or refractory MM who have received at least 2 prior lines of therapy for MM, including PIs and IMiDs (eg, Induction regimen with autologous stem cell transplant followed by maintenance is considered one line). / RRMM with measurable disease: / Serum M protein ≥0.5 g/dL measured using serum protein immunoelectrophoresis and/or / Urine M protein ≥200 mg/24 hours measured using urine protein immunoelectrophoresis and/or / Serum free light chain (sFLC) MM without measurable M protein in serum or urine per previous criteria (serum Ig free light chain ≥10 mg/dL and abnormal serum Ig kappa lambda free light chain ratio <0.26 or >1.65). / Men or woman or childbearing potential should agree to use contraception. / **Substudy 01, 06**: Anti-CD38 therapy naïve or prior exposure to such drugs with a wash out of at least 12 months after the last dose. "Exposure" is defined as at least 2 cycles of therapy. / **Substudies 02, 03**: Anti-CD38 therapy naïve or prior exposure to such drugs without being refractory but with a wash out of at least 6 months after the last dose. "Refractory" is defined as progressing within 60 days of last dose of anti-CD38 targeting therapy. / **Substudy 04:** Anti-CD38 and anti-B cell maturation antigen (BCMA) therapy (if available) prior exposed participants with RRMM. For anti-CD38, "Exposure" is defined as at least 2 cycles of therapy. For anti-BCMA therapy if available, exposure is defined by at least 2 cycles of therapy. / **Substudy 05**: Participants with RRMM with at least 2 cycles of prior exposure to anti-CD38 therapy. For participants to whom BCMA targeted therapy is available (ie, approved in their region and can be reimbursed), at least 2 cycles of prior exposure to a BCMA targeted agent is mandatory.
Exclusion Criteria:
see Link:

clinicaltrials.gov/NCT04643002

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„AZD0305 - D7230C00001“

Entities

This is a Phase I/II, modular, open-label, multicenter, dose escalation, and dose expansion/optimization study to evaluate the safety, tolerability, PK, immunogenicity, pharmacodynamics, and preliminary efficacy of AZD0305 in participants with RRMM.

Recruitment Status: RECRUITING

Condition: Multiple Myeloma
Primary Completion Date: 2025-11-11
Intervention/ Treatment: DRUG: **AZD0305**

Inclusion Criteria:
Participants must be at least 18 years of age or the legal age of consent in the jurisdiction in which the study is taking place. / Eastern Cooperative Oncology group (ECOG) performance status of ≤ 2. / Documentation of Multiple Myeloma (MM) as defined by International Myeloma Working Group (IMWG) Diagnostic Criteria for Multiple Myeloma. Site should ensure that Multiple Myeloma diagnosis is confirmed in accordance with the IMWG Diagnostic Criteria. / Participants must have one or more of the following measurable disease criteria:Serum M-protein level ≥ 0.5 g/dL. / Urine M-protein level ≥ 200 mg/24h. / Serum immunoglobulin free light chain ≥ 10 mg/dL and abnormal serum immunoglobulin kappa lambda free light chain ratio. / Adequate organ and bone marrow function assessment at screening according to the hematological, hepatic, and renal parameters listed in the CSP. / Participants must have received at least 3 prior lines of treatment which include a proteasome inhibitor (e.g., bortezomib), an immunomodulator (e.g., lenalidomide), and an anti-CD38 antibody (e.g., daratumumab).

Exclusion Criteria:
Participants exhibiting clinical signs of central nervous system involvement of MM. / Participants with known COPD, or previous history of ILD. / Participants with known moderate or severe persistent asthma within the past 5 years, or uncontrolled asthma of any classification. / Participants who have severe cardiovascular disease which is not adequately controlled. / Participants who have a history of immunodeficiency disease. / Participants with peripheral neuropathy ≥ Grade 2. / Primary refractory MM. / Participants who have previously received anti-GPRC5D or MMAE-containing treatment. / Participants who have previously received allogenic stem cell transplant, or participant has received autologous stem cell transplant within 3 months before the first dose of study intervention.

see Link:

clinicaltrials.gov/NCT06106945

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The goal of this clinical trial is to learn about the safety and efficacy of the drug combination belantamab mafodotin and venetoclax, with or without the addition of dexamethasone, in patients with relapsed/refractory Multiple Myeloma bearing the translocation t(11;14)

Recruitment Status: RECRUITING

Condition: Multiple Myeloma, Multiple Myeloma in Relapse
Primary Completion Date: 2026-11
Intervention/ Treatment: DRUG: **Belantamab mafodotin, Venetoclax**

Inclusion Criteria:

Subjects must be ≥ 18 years of age. / Subjects must have an Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 2 / Subjects must voluntarily sign and date an in-formed consent form
Subjects must have had documented Multiple Myeloma requiring treatment as defined by the criteria below: Monoclonal plasma cells in the bone marrow > 10% and/or presence of a biopsy proven plasmacytoma at some point in their disease history requiring treatment according diag-nostic criteria (IMWG updated criteria 2014, Rajkumar et al. 2014) with measurable dis-ease at screening (serum M-protein > 500 mg/dL or urine M protein 200 mg/24h, in case of oligosecretory MM serum free light chain > 10mg/dL and abnormal kap-pa/lambda free light chain ratio) / Cytogenetics/FISH confirming t(11;14)
Prior treatment requirements: Phase 1: Subjects must have received at least 4 prior treatments (induction, high-dose, consolida-tion and maintenance is considered as one treatment line) and are refractory to at least one proteasome inhibitor, at least one im-munomodulatory drug and at least one mon-oclonal anti CD38 antibody. / Subjects must have documented evidence of progressive disease during their last treat-ment. / **Phase 2:** Subjects must have received at least 1 prior treatment line (induction, high-dose, consoli-dation and maintenance is considered as one treatment line). All patients must have received at least one proteasome inhibitor and at least one immunomodulatory agent and at least one anti CD38 monoclonal anti-body. / Subjects must have documented evidence of progressive disease on or after the last treatment line. / Phase 1+2 e. Subjects with a history of autologous SCT are eligible for study participation provided the following eligibility criteria are met: i. ASCT was >100 days prior to initiating study treatment, and ii. No active bacterial, viral, or fungal in-fection(s) present. / Subjects must have adequate organ function, defined as follows: a. Hemoglobin ≥8.0 g/dL (without transfusion of red blood cells for the past 14 days) b. Absolute neutrophil count ≥ 1.5 x109/L (with-out growth factor support for the past 14 days) c. Platelet count more or equal 75 x109/L (with-out growth factor or platelet stimulating agents for the past 14 days) d. Adequate hepatic function per local laborato-ry reference range as follows: i. Aspartate aminotransferase (AST) ≤ 2,5 x upper limit of normal (ULN); ii. Alanine aminotransferase (ALT) ≤ 2.5 x ULN iii. Total bilirubin ≤ 1.5 x ULN, except in subjects with congenital bilirubinemia, such as Gilbert syndrome (direct bili-rubin ≤ 1.5 x ULN). Isolated bilirubin ≥1.5xULN is acceptable if bilirubin is fractionated and direct bilirubin <35%. / e. Subjects must have adequate renal function as demonstrated by eGFR ≥30 mL/min/ 1.73 m2 as calculated by Modified Diet in Renal Disease (MDRD) formula f. Spot urine (albumin/creatinine ratios (spot urine) <500 mg/g (56 mg/mmol) OR Urine Dipstick Negative/trace (if 1+ only eligible if confirmed <500 mg/g (56 mg/mmol) by albumin/creatinine ratio (spot urine from first void) g. Corrected serum calcium ≤ 14 mg/dL (≤3,5 mmol/L); or free ionized calcium < 6,5 mg/dL (<1,6 mmol/L) / A female participant is eligible to participate if she is not pregnant or breastfeeding, and at least one of the following conditions applies: / Is not a woman of childbearing potential (WOCBP) **OR** Is a WOCBP and using a contraceptive method that is highly effective / Male participants are eligible to participate if they agree to the refrain from donating sperm and either bei abstinent from heterosexual intercourse or agree to use a highly effective contraceptive method during the intervention period and for 6 months after the last dose of study treatment to allow for clearance of any altered sperm / All subjects must agree to refrain from donating blood while on study drug and for 28 days after discontinuation from this study treatment. / All subjects must agree not to share study medication. / All prior treatment-related toxicities (defined by National cancer Institute- Common Toxicity Criteria for Adverse Events (NCI-CTCAE), version 5.0) must be ≤ Grade 1 at the time of en-rolment except for alopecia.

see Link: clinicaltrials.gov/NCT05853965

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A Phase 3, Multicenter, Randomized, Open Label Study of ABBV-383 Compared With Standard Available Therapies in Subjects With Relapsed or Refractory Multiple Myeloma (3L+ RRMM Monotherapy Study)

Recruitment Status: RECRUITING

Condition: Multiple Myeloma
Primary Completion Date: 2027-12-05
Intervention/ Treatment: DRUG: **ABBV-383/ Carfilzomib/ Pomalidomide/ Elotuzumab/ Selinexor/ Bortezomib/ Dexamethasone**

Inclusion Criteria:
Eastern Cooperative Oncology Group (ECOG) performance of <= 2. / Diagnosis of relapsed/refractory (R/R) Multiple Myeloma (MM) during or after the participant's last treatment as stated in the protocol. Must have measurable disease with at least 1 of the following assessed within 28 days of enrollment: / Serum M-protein >= 0.5 g/dL (>= 5 g/L). / Urine M-protein >= 200 mg/24 hours. / In participants without measurable serum or urine M protein, serum free light chain (FLC) >= 100 mg/L (10 mg/dL) (involved light chain)and an abnormal serum kappa lambda ratio. / Must have received at least 2 or more lines of therapy, including a proteasome inhibitor (PI), an immunomodulatory imide (IMiD), and an anti-CD38 monoclonal antibody (mAb). / Must be naïve to treatment with B-cell maturation antigen (BCMA)-targeted therapy. / Must be eligible to receive the Investigator's choice standard available therapy (SAT) based on approved prescribing information, previous MM treatment history, and institutional guidelines.
Exclusion Criteria:
Clinically significant (per Investigator's judgment) drug or alcohol abuse within the last 6 months. / Clinically significant conditions such as but not limited to the following: neurologic, psychiatric, endocrine, metabolic, immunologic, cardiovascular, pulmonary, or hepatic disease within the last 6 months that would adversely affect the participant's participation in the study. / Central nervous system involvement of MM.
see Link:

clinicaltrials.gov/NCT06158841

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A Multicenter, Phase 1b, Open-label Study of ABBV-383 Administered Subcutaneously in Subjects With Relapsed or Refractory Multiple Myeloma

Recruitment Status: RECRUITING

Condition: Multiple Myeloma
Primary Completion Date: 2027-02-21
Intervention/ Treatment: DRUG: **ABBV-383 (SC)/ ABBV-383 (IV)**

Inclusion Criteria:
Eastern Cooperative Oncology Group (ECOG) performance of <= 2. / Participants with relapsed or refractory Multiple Myeloma who have received 3-5 prior lines of therapies and with prior triple class exposure including a proteasome inhibitor, anti-CD38 monoclonal antibody and an immunomodulatory drug. / Must be naïve to treatment with ABBV-383.
Exclusion Criteria:
Received B-cell maturation antigen (BCMA)xCD3 bispecific antibody.
see Link:

clinicaltrials.gov/NCT06223516

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Phase 3 Study of Teclistamab in Combination With Lenalidomide and Teclistamab Alone Versus Lenalidomide Alone in Participants With Newly Diagnosed Multiple Myeloma as Maintenance Therapy Following Autologous Stem Cell Transplantation

Recruitment Status: RECRUITING

Condition: Multiple Myeloma
Primary Completion Date: 2028-04
Intervention/ Treatment: DRUG: **Teclistamab/ Lenalidomide**

Inclusion Criteria:
Must have a new diagnosis of Multiple Myeloma according to IMWG criteria and have received induction +/- consolidation. / Must have received only one line of therapy and achieved at least a partial response (≥PR) as per IMWG 2016 response criteria (Kumar 2016) without evidence of progression at the time of first treatment dose. / Must not be intolerant to the starting dose of lenalidomide. / Must not have received any maintenance therapy. / Have an ECOG performance status score of 0, 1, or 2 at screening and immediately prior to the start of administration of study treatment / Have clinical laboratory values within prespecified range.

Exclusion Criteria:
Received any prior BCMA-directed therapy. / Any previous therapy with an immune cell redirecting agent or gene modified adoptive cell therapy (eg, chimeric antigen receptor modified T cells, NK cells). Discontinued treatment due to any AE related to lenalidomide as determined by the investigator. / Progressed on Multiple Myeloma therapy at any time prior to screening. / Received a cumulative dose of corticosteroids equivalent to ≥140 mg of prednisone within the 14 days prior to first treatment dose. / Received a live, attenuated vaccine within 4 weeks before first treatment dose. Non-live vaccines or non-replicating authorized for emergency use (eg. COVID-19) are allowed.

see Link:

clinicaltrials.gov/NCT05243797

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A Dose Escalation and Expansion Study of ABBV-383 in Combination With Anti-cancer Regimens for the Treatment of Patients With Relapsed/Refractory Multiple Myeloma

Recruitment Status: RECRUITING

Condition: Relapsed/Refractory Multiple Myeloma
Primary Completion Date: 2028-11-29
Intervention/ Treatment: DRUG: **ABBV-383/ Dexamethasone/ Lenalidomide/ Pomalidomide/ Nirogacestat/ Daratumumab**

Inclusion Criteria:
Eastern Cooperative Oncology Group (ECOG) performance of <= 2. / Must have confirmed diagnosis of Relapsed/Refractory (R/R) Multiple Myeloma (MM) with documented evidence of progression during or after the participant's last treatment regimen based on the investigator's determination of the International Myeloma Working Group (IMWG) criteria. / Must have measurable disease as outlined in the protocol. / Must be naïve to treatment with ABBV-383 and must have never received BCMA-targeted therapy. Participants who have received targeted therapy against non-BCMA targets will not be excluded.
Has received prior MM treatment in Arms A, B, C, and D.

Exclusion Criteria:
Received a peripheral autologous stem cell transplant (SCT) within 12 weeks, or an allogeneic SCT within 1 year of the first dose of study drug treatment. / Unresolved adverse event (AE)s >= Grade 2 (National cancer Institute [NCI] Common Terminology Criteria for Adverse Events [CTCAE] version 5.0) from prior anticancer therapy. / Known central nervous system involvement Multiple Myeloma (MM). Has any of the following conditions: Nonsecretory MM. / Active Plasma cell leukemia i.e., either 20% of peripheral white blood cells or > 2.0 × 10^9L circulating plasma cells by standard differential. / Waldenstrom's macroglobulinemia. / Light chain amyloidosis. / Polyneuropathy, organomegaly, endocrinopathy, monoclonal protein and skin changes (POEMS) syndrome. / Major surgery within 4 weeks prior to first dose or planned study participation. / Acute infections within 14 days prior to first dose of study drug requiring therapy (antibiotic, antifungal or antiviral). / Uncontrolled diabetes or hypertension within 14 days prior to first dose. / Peripheral neuropathy >= Grade 3 or >= Grade 2 with pain within 2 weeks prior to first dose. / Known active infection of evidence of active hepatitis B, evidence of active hepatitis C, human immunodeficiency virus.

see Link:

clinicaltrials.gov/NCT05259839

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Phase II Trial for Newly Diagnosed Low-risk Multiple Myeloma Patients Comparing 6 Cycles of Isatuximab With Lenalidomide/Bortezomib/Dexamethasone (I-VRD) Compared to 3 Cycles of I-VRD Followed by One Cycle of High-dose Therapy and Both Arms Followed by Maintenance Therapy With I-R.

Recruitment Status: RECRUITING

Condition: Newly Diagnosed Multiple Myeloma
Primary Completion Date: 2027-08
Intervention/ Treatment: DRUG: **Isatuximab/ Lenalidomide/ Bortezomib/ Dexamethasone**_OTHER:**autologous stem cell transplant**

Inclusion Criteria:

newly diagnosed, untreated, symptomatic, documented myeloma (according to the revised Hypercalcaemia, renal dysfunction, Anemia and bone lesions (CRAB) criteria 2014, see Appendix 1) with clonal bone marrow (BM) plasma cells ≥10% or biopsy-proven osseous or extramedullary plasmacytoma and any one or more of the following myeloma defining events: / **I.** Hypercalcemia: serum calcium >0,25 mmol/L (>1 mg/dl) higher than the upper limit of normal or >2,75 mmol/L (>11 mg/dL) / **II.** Renal insufficiency: serum creatinine > 177 µmol/l (>2 mg/dl) / **III**. Anemia: hemoglobin value of >20 g/l below the lower limit of normal or a hemoglobin value lower than 10g/dl. / **IV.** Bone lesions: one or more osteolytic lesions on skeletal radiography, CT, or PET- CT (positron emission tomography) V. Clonal BM plasma cell percentage ≥60% VI. Involved: uninvolved serum free light chain ratio ≥100 VII. >1 focal lesion on MRI examination / **Presence of measurable disease:**I. Serum M-protein ≥ 0.5 g/dL or urine M-protein ≥ 200 mg/24 hours. II. Involved FLC (free light chain) level ≥ 10 mg/dl, provided sFLC (free light chain) ratio is abnormal. / R-ISS stage I33 (see appendix 2) / Standard gene expression pattern of isolated plasma cell based on SKY92 GEP assay / Must be ≥ 18 and ≤70 years at the time of signing the informed consent form. / Must be able to adhere to the study visit schedule and other protocol requirements in the investigator's opinion. / WHO (see Appendix 3) performance status 0-2 (WHO=2 is allowed only if caused by MM and not by co-morbid conditions). / Ability to understand and willingness to sign written informed consent. Signed informed consent must be obtained before any study specific procedure. / Suitable for high-dose melphalan and stem cell retransfusion. / Subjects must have adequate vascular access for leukapheresis / ….

see Link:

clinicaltrials.gov/NCT05665140

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A Randomized Phase III Trial Assessing Iberdomide Versus Iberdomide Plus Isatuximab Maintenance Therapy Post Autologous Hematopoietic Stem-Cell Transplantation in Patients with Newly Diagnosed Multiple Myeloma

Recruitment Status: RECRUITING

Condition: Multiple Myeloma
Primary Completion Date: 2028-12
Intervention/ Treatment: DRUG: **Iberodomide/ Isatuximab/ Dexamethasone**

Inclusion Criteria:
Prior inclusion and treatment within the GMMG-HD8 / DSMM XIX trial / Received at least one cycle high dose melphalan therapy (HDM) and autologous stem cell transplantation (ASCT) / At least Partial Response (PR) according to IMWG criteria at inclusion in the trial / Age of at least 18 years at trial inclusion / WHO performance status of 0, 1, or 2 / Negative pregnancy test at inclusion (women of childbearing potential) /
For all men and women of childbearing potential: patients must be willing and capable to use adequate contraception during the complete therapy /
Ability of patient to understand character and individual consequences of the clinical trial / Written informed consent (must be available before enrolment in the trial)

Exclusion Criteria:
Subjects with gastrointestinal disease that may significantly alter the absorption of iberdomide / Patient has known hypersensitivity (or contraindication) to any of the components of study therapy that are not amenable to premedication with steroids or H1 blockers and that would prohibit further treatment with these agents (e.g. known intolerance or hypersensitivity to infused proteins products, sucrose, histidine, and polysorbate 80 as well as intolerance to arginine and Poloxamer 188) / Patients with a history of serious allergic reaction to another immunomodulatory agent (thalidomide, lenalidomide, or pomalidomide)", as angioedema and severe dermatologic reactions, including Grade 4 rash and exfoliative or bullous rash / Patients currently being treated with strong inhibitors or inducers of CYP3A4/5 / Systemic AL amyloidosis (except for localized AL amyloidosis limited to the skin or the bone marrow), plasma cell leukemia or polyneuropathy, organomegaly, endocrinopathy, monoclonal-protein and skin abnormalities or Waldenström macroglobulinemia. / Previous systemic anti-myeloma treatment other than administered within the GMMG-HD8 / DSMM XIX trial (including up to two cycles cycle high dose melphalan therapy (HDM) and autologous stem cell transplantation (ASCT). Local, consolidative radiotherapy for myeloma disease is permitted unless performed in case of progressive disease according to IMWG criteria / Severe cardiac dysfunction (NYHA classification III-IV) /
Significant hepatic dysfunction (ASAT and/or ALAT ≥ 3 times normal level and/or serum bilirubin ≥ 1.5 times normal level if not due to hereditary abnormalities as Gilbert's disease), unless related to MM or HDM/ASCT. / Patients with active or uncontrolled hepatitis B or C or detectable liver disease due to hepatitis B or C. In case of history of hepatitis B or C, it must be clarified whether it has been overcome and negative circulating HBV-DNA or HCV-RNA must be provided. Positive hepatitis B status may only be acceptable in absence of circulating HBV-DNA or signs of chronic or acute infection and if an adequate prophylaxis is being implemented during the course of the study. Prophylaxis for patients with history of hepatitis B or C should be set on a patient individual basis. / HIV positivity / Patients with active, uncontrolled infections / Patients with severe renal insufficiency (Creatinine Clearance < 30ml/min) or requiring hemodialysis / Patients with peripheral neuropathy or neuropathic pain, grade 2 or higher (as defined by the NCI Common Terminology Criteria for Adverse Events (NCI CTCAE, version 5.0) / Patients with a history of any active malignancy during the past 5 years with the exception of following malignancies after curative therapy: basal cell carcinoma of the skin, squamous cell skin carcinoma, stage 0 cervical carcinoma or any in situ malignancy. A history of an early stage malignancy during the past 5 years may be acceptable, however, in this case the GMMG study office has to be consulted prior to study inclusion / Patients with acute diffuse infiltrative pulmonary and/or pericardial disease / Autoimmune haemolytic Anemia with positive indirect Coombs test or immune thrombocytopenia / Platelet count < 75 x 109/l / Haemoglobin ≤ 8.0 g/dl, unless related to MM
Absolute neutrophil count (ANC) < 1.0 x 109/l (the use of colony stimulating factors within 14 days before the test is not allowed) / Corrected serum calcium > 14 mg/dl (> 3.5 mmol/l) / Unable or unwilling to undergo thromboprophylaxis / Pregnancy and lactation / Participant has any concurrent severe and/or uncontrolled medical condition or psychiatric disease that is likely to interfere with study procedures or results, or that in the opinion of the investigator would constitute a hazard for participating in this study or that confounds the ability to interpret data from the study / Subjects, who are committed to an institution by virtue of an order issued either by the judicial or the administrative authorities / Participation in other interventional clinical trials. This does not include long-term follow-up periods without active drug treatment of previous studies during the last 6 months.

see Link:

clinicaltrials.gov/NCT06216158

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG

Universitätsklinikum Hamburg-Eppendorf

A Phase 3, Two-Stage, Randomized, Multicenter, Open-Label Study Comparing Mezigdomide (CC-92480), Bortezomib and Dexamethasone (MEZIVd) Versus Pomalidomide, Bortezomib and Dexamethasone (PVd) in Subjects With Relapsed or Refractory Multiple Myeloma (RRMM)

Recruitment Status: RECRUITING

Condition: Reapsed or Refractory Multiple Myeloma
Primary Completion Date: 2025-11-03
Intervention/ Treatment: DRUG: **Merzigdomide/ Pomalidomide/ Bortezomib/ Dexamethasone**

Inclusion Criteria:
Participant has documented diagnosis of MM and measurable disease, defined as any of the following:.
i) M-protein ≥ 0.5 grams per deciliter (g/dL) by serum protein electrophoresis (sPEP) or.
ii) M-protein ≥ 200 milligrams (mg) per 24-hour urine collection by urine protein electrophoresis (uPEP).
iii) For participants without measurable disease in sPEP or uPEP: serum free light chain (sFLC) levels > 100 mg/L (10 mg/dL) involved light chain and an abnormal kappa/lambda FLC ratio.
Participants received 1 to 3 prior lines of antimyeloma therapy.
Participants achieved minimal response [MR] or better to at least 1 prior antimyeloma therapy.
Exclusion Criteria
- Participant has had progression during treatment or within 60 days of the last dose of a proteasome inhibitor, except as noted below:.
i) Subjects who progressed while being treated with, or within 60 days of last dose of bortezomib maintenance given once every 2 weeks (or less frequently) are not excluded.
ii) Participants who progressed while being treated with ixazomib monotherapy maintenance ≥ 6 months prior to the time of starting study treatment are not excluded.
For participants with prior treatment of a bortezomib containing regimen, the best response achieved was not a minimal response (MR) or better, or participant discontinued bortezomib due to toxicity.
Participant has had prior treatment with mezigdomide or pomalidomide.
Other protocol-defined Inclusion/Exclusion criteria apply.
see Link:

clinicaltrials.gov/NCT05519085

Study Test Center	PI / SC	Phone	E-Mail
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UKSH Kiel Stem cell and immunotherapy	Dr. med. Natalie Schub Kerstin Eilts (SC)	0431 50022711 0431 500 22751	Natalie.Schub@uksh.de Kerstin.Eilts@uksh.de

Universitäres Cancer Center HAMBURG
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A Phase 1b/2 Dose-Escalation and Cohort-Expansion Study to Determine the Safety and Efficacy of BGB-11417as Monotherapy, in Combination With Dexamethasone, Dexamethasone/Carfilzomib, Dexamethasone/Daratumumab, and Dexamethasone/Pomalidomide in Patients With Relapsed/Refractory Multiple Myeloma and t(11;14)

Recruitment Status: RECRUITING

Condition: Reapsed / Refractory Multiple Myeloma
Primary Completion Date: 2026-11
Intervention/ Treatment: DRUG: **Sonrotoclax/ Dexamethasone/ Carfilzomib/ Daratumumab/ Pomalidomide**

Inclusion Criteria:
Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 / A confirmed diagnosis of Multiple Myeloma (must have an M-component in serum and/or urine) / Measurable disease defined as: i. M-spike ≥ 500mg/dL, or ii. Urine protein M-spike of ≥ 200 mg/day, or iii. Serum free light chains ≥ 10 mg/dL, and an abnormal κ:λ ratio / Participant has documented relapsed or progressive MM on or after any regimen or who are refractory to the most recent line of therapy. / i. Relapsed MM is defined as previously treated MM that progresses and requires initiation of salvage therapy but does not meet the criteria for refractory MM. / ii. Refractory MM is defined as disease that is nonresponsive (failure to achieve minimal response or development of progressive disease) while on primary or salvage therapy or progresses within 60 days of last therapy. / In Part 1 should have relapsed or progressive disease and have had ≥ 3 prior lines of therapy including a proteasome inhibitor, an IMiD, and an anti-CD38 monoclonal antibody, and no more available approved therapies. / Participants in Part 2 should have relapsed or progressive disease and have had ≥ 1 prior line of therapy / Prior treatment with carfilzomib is allowed but the patient must not be considered carfilzomib refractory by the investigator. / Positivity for t(11;14) translocation must be confirmed by validated fluorescence in situ hybridization (FISH) testing assay in a pre-defined laboratory / a. fresh bone marrow aspirate sample must be collected at screening and sent to central laboratory for t(11;14) FISH testing. / Adequate organ function defined as:Hemoglobin ≥ 8.0 g/dL within 7 days before first dose of study treatment, (transfusions, in accordance with institutional guidelines, are permitted) / Platelet count ≥ 75,000/µL, within 7 days before first dose of study treatment, independent of growth factor support and transfusions / Absolute neutrophil count (ANC) ≥ 1000/mm^3 within 7 days before first dose of study treatment / Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) ≤ 3 x upper limit of normal (ULN) and total bilirubin ≤ 2.0 x ULN N (total bilirubin must be < 3 x ULN for patients with Gilbert's syndrome)
see Link:

clinicaltrials.gov/NCT04973605

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
Universitätsklinikum Hamburg-Eppendorf

A Phase 3, Randomized, Open-Label, Multicenter Study to Compare the Efficacy and Safety of BMS-986393, a GPRC5D-directed CAR-T Cell Therapy, Versus Standard Regimens in Adult Participants With Relapsed or Refractory and Lenalidomide-refractory Multiple Myeloma

Recruitment Status: RECRUITING

Condition: Reapsed / Refractory Multiple Myeloma
Primary Completion Date: 2027-1-30
Intervention/ Treatment: DRUG: **BMS-986393/ Cyclophosphamide/ Fludarabine/ Daratumumab/ Pomalidomide, Dexamethasone, Carfilzomib**

Inclusion Criteria:
Participants must have relapsed or refractory Multiple Myeloma (RRMM).
Participants must have received at least 1 but no greater than 3 prior Multiple Myeloma (MM) regimens which may include a proteasome inhibitor (PI), an immunomodulatory drug (IMiD), and an anti-CD38 monoclonal antibody, and be refractory to lenalidomide (LEN) (progression on or within 60 days of completing LEN therapy).
Participants must have a documented diagnosis of MM as per International Myeloma Working Group Criteria.
Participants must have measurable disease during screening.
Participants must have adequate organ function.
Participants must have an Eastern Cooperative Oncology group performance status 0 or 1.
Exclusion Criteria
Participants must not have known active or history of central nervous system (CNS) involvement of Multiple Myeloma (MM).
Participants must not have solitary plasmacytomas or non-secretory myeloma without other evidence of measurable disease.
Participants must not need urgent treatment due to rapidly progressing MM.
Other protocol-defined Inclusion/Exclusion criteria apply.
see Link:

clinicaltrials.gov/NCT06615479

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A phase 3, randomized,open-label Study to compare the efficacy and safety of Anitocabtagene Autoleucel versus standard of care therapy in Participants with relapsed/refractory Multiple Myeloma

Recruitment Status: RECRUITING

Condition: Multiple Myeloma
Primary Completion Date: 2028-07
Intervention/ Treatment: DRUG: Anitocabtagene Autoleucel/ Cyclophosphamide/ Fludarabine/ Pomalidomide/ BortezomibCevostomab/ Lenalidomide / Dexamethasone/ Daratumumab/ Carfilzomib

Inclusion Criteria:
Documented historical diagnosis of Multiple Myeloma (MM) / Received 1 to 3 prior lines of antimyeloma therapy, including an immunomodulatory drug (IMiD) and an anti-cluster of differentiation 38 (CD38) monoclonal antibody (mAb). A minimum of 2 consecutive cycles of an IMiD and an anti-CD38 mAb in any prior line of therapy is required. The IMiD and anti-CD38 mAb do not need to be from the same regimen in the prior line(s) of therapy. / Documented evidence of progressive disease by IMWG criteria based on the investigator's determination on or within 12 months of the last dose of the last regimen / Measurable disease at screening per IMWG, defined as any of the following: Serum M-protein level ≥ 0.5 g/dL or urine M-protein level ≥ 200 mg/24 hours**; or** Light chain MM without measurable disease in the serum or urine: serum free light chain ≥ 10 mg/dL and abnormal serum free light chain ratio / Only individuals who are candidates to receive at least 1 of the 4 SOCT regimens (PVd, DPd, KDd, or Kd), as determined by the investigator, should be considered for this study / Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 / Females of childbearing potential must have a negative serum or urine pregnancy test with a sensitivity of at least 25 mIU/mL (females who have undergone surgical sterilization or who have been postmenopausal for at least 2 years are not considered to be of childbearing potential)

Exclusion Criteria:
Prior B-cell maturation antigen (BCMA)-targeted therapy / Prior T-cell engager therapy / Prior CAR therapy or other genetically modified T-cell therapy / Active or prior history of central nervous system (CNS) or meningeal involvement of MM / Cardiac atrial or cardiac ventricular MM involvement / History of or active plasma cell leukemia, Waldenstrom's macroglobulinemia, POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes), or amyloidosis / Active malignancy (other than MM) requiring ongoing treatment for disease control within the last 24 months. Myelodysplastic syndrome (even without ongoing treatment) is not permitted. / Prior auto-SCT within 12 weeks before randomization / Prior allogeneic stem cell transplant (allo-SCT) / High-dose (eg, cumulative > 70 mg prednisone or equivalent) systemic steroid therapy or any other form of immunosuppressive therapy within 14 days before randomization / Live vaccine ≤ 4 weeks before randomization / Contraindication to fludarabine or cyclophosphamide / History of allergy or hypersensitivity to any study agent or study drug components. Individuals with a history of severe hypersensitivity reaction to dimethyl sulfoxide (DMSO) are excluded. / Life expectancy < 12 weeks

see Link:

clinicaltrials.gov/NCT06413498

Study Test Center	PI / SC	Phone	E-Mail
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A Phase 3 Randomized Study Comparing Teclistamab in Combination With Daratumumab SC and Lenalidomide (Tec-DR) and Talquetamab in Combination With Daratumumab SC and Lenalidomide (Tal-DR) Versus Daratumumab SC, Lenalidomide, and Dexamethasone (DRd) in Participants With Newly Diagnosed Multiple Myeloma Who Are Either Ineligible or Not Intended for Autologous Stem Cell Transplant as Initial Therapy

Recruitment Status: RECRUITING

Condition: Multiple Myeloma
Primary Completion Date: 2031-04-30
Intervention/ Treatment: DRUG: **Teclistamab/ Daratumumab/ Lenalidomide/ Dexamethasone/ Talquetamab**

Inclusion Criteria:
Have a diagnosis of Multiple Myeloma according to the International Myeloma Working Group (IMWG) diagnostic criteria / Be newly diagnosed and not considered a candidate for high-dose chemotherapy with autologous stem cell transplant (ASCT) due to: ineligible due to advanced age OR; ineligible due to the presence of comorbid condition(s) likely to have a negative impact on tolerability of high-dose chemotherapy with ASCT OR; deferral of high-dose chemotherapy with ASCT as initial treatment / Have an Eastern Cooperative Oncology Group (ECOG) performance status score of 0 to 2 /
A participant must agree not to be pregnant, breastfeeding, or planning to become pregnant while enrolled in this study or within 6 months after the last dose of study treatment /
A participant must agree not to plan to father a child while enrolled in this study or within 100 days after the last dose of study treatment

Exclusion Criteria:
Received any prior therapy for Multiple Myeloma or smoldering myeloma other than a short course of corticosteroids (not to exceed total of 160 milligrams [mg] dexamethasone or equivalent). In addition, received a cumulative dose of systemic corticosteroids equivalent to greater than or equals to (>=) 20 mg of dexamethasone within 14 days before randomization / Had plasmapheresis within 28 days of randomization / Had a stroke, transient ischemic attack, or seizure within 6 months prior to randomization / Known allergies, hypersensitivity, or intolerance to teclistamab or talquetamab excipients /
Known contraindications to the use of daratumumab or lenalidomide per local prescribing information / Myeloma Frailty Index of >=2 with the exception of participants who have a score of 2 based on age alone

see Link:

clinicaltrials.gov/NCT05552222

Study Test Center	PI / SC	Phone	E-Mail
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A randomized, open-label, controlled phase 3 study comparing induction treatment with daratumumab, lenalidomide, and dexamethasone followed by linvoseltamab with continued treatment with daratumumab, lenalidomide, and dexamethasone in newly diagnosed patients with multiple myeloma who are not eligible for transplantation.

Condition: Multiple Myeloma
Primary Completion Date: 2036-12
Phase: III
Intervention/ Treatment: DRUG: **Linvoseltamab/ Daratumumab/ Lenalidomide/ Dexamethasone**

Inclusion Criteria:
Participants must have confirmed diagnosis of symptomatic MM per IMWG criteria. / Participants must not be considered a candidate for high-dose chemotherapy (HDT) and ASCT, as described in the protocol. / Participants must have measurable disease as defined in the protocol. / Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2. / Participants must have clinical laboratory values within a prespecified range.

Exclusion Criteria:
International Myeloma Working Group Frailty Index of 2 with the exception of participants who have a score of 2 based on age alone. / Participants who defer transplant due to personal preference. 1.Participants with non-secretory MM, active plasma cell leukemia, known light-chain (AL) amyloidosis in the presence of a concurrent diagnosis of myeloma, any other form of amyloidosis, Waldenström macroglobulinemia, or known POEMS syndrome. / Any prior therapy for monoclonal gammopathy of undetermined significance (MGUS), smoldering multiple myeloma (SMM), or MM, with the exception of: / focal radiation and/or a short course of corticosteroids as defined in the protocol. / Participants who have received or are receiving any investigational agent or cell therapy with known or suspected activity against MM / Participants who have known central nervous system (CNS) or meningeal involvement with MM or known or suspected progressive multifocal leukoencephalopathy (PML), a history of a neurocognitive condition or CNS movement disorder, OR a history of seizure, transient ischemic attack (TIA), stroke or seizure within 12 months prior to study C1D1. / Participants who have uncontrolled intercurrent illness. / Known contraindications to the use of daratumumab or lenalidomide per local prescribing information. / History of allogeneic hematopoietic stem cell transplantation or solid organ transplant at any time. / NOTE Other protocol defined inclusion/exclusion criteria apply.
see Link:

clinicaltrials.gov/NCT06932562

Study Test Center	PI / SC	Phone	E-Mail
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Myelodysplastic Syndrome (MDS)

continue...

Contact at UCC Hamburg
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Currently no study options

continue...

Anemias

continue...

Contact at UCC Hamburg
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Currently no study options

continue...

Immune thrombozytopenia (ITP)

continue...

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Currently no study options

continue...

Amyloidosis

continue...

Contact at UCC Hamburg
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This is an open-label, multi-center pivotal Phase 3 study to visually and quantitatively assess PET images obtained after single application of 300 MBq [18F]florbetaben and PET scanning of patients with suspected cardiac amyloidosis.

Recruitment Status: RECRUITING

Condition: Cardiac Amyloidosis/ AL Amyloidosis/ ATTR Amyloidosis
Primary Completion Date: 2025-03
Intervention/ Treatment: DRUG: **[18F]florbetaben**

Inclusion Criteria:
Males and females age ≥18 years / Able to understand, sign and date written informed consent / Written informed consent must be obtained before any assessment is performed /
Subjects being considered for a possible diagnosis of cardiac amyloidosis by One of the following conditions: / Established systemic amyloidosis without proven cardiac involvement, / Known plasma cell dyscrasia (MGUS, Multiple Myeloma), / Pathological free light chain levels in urine or serum, / Presence of heart failure with preserved ejection fraction / **AND** one of the following parameters, indicative of cardiac manifestation: / Mean (left ventricular (LV) wall + septum) thickness >12mm as measured by echocardiography in absence of other known cause of left ventricular hypertrophy (LVH), / NT-proBNP >335 ng/L / Planned diagnostic procedure to establish diagnosis and cardiac involvement (e.g., endomyocardial biopsy or extracardiac biopsy in conjunction with cardiac magnetic resonance imaging/echocardiography or bone scintigraphy) / Female subjects must be documented by medical records or physician's note to be either surgically sterile (by means of hysterectomy, bilateral salpingectomy, or bilateral oophorectomy) or post-menopausal for at least 1 year (no menses for 12 months without an alternative medical cause). If they are of child-bearing potential, they must commit to use of a highly effective contraceptive measure for at least one week following the PET scan / Male subjects and their partners of childbearing potential must commit to the use of a highly effective method of contraception for a minimum of 90 days following the PET scan / Male subjects must commit to not donate sperm for a minimum of 90 days after the PET scan
Exclusion Criteria:
Any known allergic reactions or hypersensitivity towards any compound of the study drug / Severe hepatic impairment (AST/ALT >5 x ULN; bilirubin >3 x ULN) / Inability to lay flat for up to 60 min / Pregnant, lactating or breastfeeding / Unwilling and/or unable to cooperate with study procedures / Having been administered a radiopharmaceutical within 10 radioactive half-lives prior to study drug administration in this study
see Link:

clinicaltrials.gov/NCT05184088

Study Test Center	PI / SC	Phone	E-Mail
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Primary CNS lymphomas (PCNSL)

continue...

Contact at UCC Hamburg
PD Dr. med. Minna Voigtländer, Tel.: 0152-22817911

This phase III study investigates if a de-escalated induction treatment in newly diagnosed primary CNS lymphoma is superior to the standard MATRix protocol in terms of event free survival.

Recruitment Status: RECRUITING

Condition: Primary Central Nervous System Lymphoma
Primary Completion Date: 2027-08
Intervention/ Treatment: DRUG: **Experimental Treatment: one course Rituximab/HD-Methotrexate, two courses of MATRix_Control intervention: four courses of MATRix**

Inclusion Criteria:
Immunocompetent patients with newly diagnosed primary diffuse large B-cell lymphoma of the central nervous system (PCNSL). / Male or female patients aged 18-65 years irrespective of ECOG or 66-70 years with ECOG Performance Status ≤2. / Histologically or cytologically assessed diagnosis of B-cell lymphoma by local pathologist. Diagnostic sample obtained by stereotactic or surgical biopsy, CSF cytology examination or vitrectomy. / Disease exclusively located in the CNS. / At least one measurable lesion. / Previously untreated patients (previous or ongoing steroid treatment admitted) /
Negative pregnancy test / Written informed consent obtained according to international guidelines and local laws by patient or authorized legal representative in case patient is temporarily legally not competent due to his or her disease. / Ability to understand the nature of the trial and the trial related procedures and to comply with them.

Exclusion Criteria:
Congenital or acquired immunodeficiency including HIV infection and previous organ transplantation. / Systemic lymphoma manifestation (outside the CNS). / Primary vitreoretinal lymphoma without manifestation in the brain parenchyma or spinal cord / Previous or concurrent malignancies with the exception of surgically cured carcinoma in situ of the cervix, carcinoma of the skin or other kinds of cancer without evidence of disease for at least 5 years. / Previous Non-Hodgkin lymphoma at any time. / Inadequate renal function (clearance < 60 ml/min). / Inadequate bone marrow, cardiac, pulmonary or hepatic function according to investigator´s decision / Active hepatitis B or C disease. / Concurrent treatment with other experimental drugs or participation in an interventional clinical trial with study medication being administered within the last 30 days before the start of this study. / Third space fluid accumulation > 500 ml. / Hypersensitivity to study treatment or any component of the formulation. /
Taking any medications that are likely to cause interactions with the study medication / Known or persistent abuse of medication, drugs or alcohol. / Active COVID-19-infection or non-compliance with the prevailing hygiene measures regarding the COVID-19 pandemic / Patients without legal capacity who are unable to understand the nature, significance and consequences of the trial and without designated legal representative. / Previous participation in this trial. / Persons who are in a relationship of dependency/employment with the sponsor and/or the investigator. /
Any familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule / Current or planned pregnancy, nursing period
For fertile patients: Failure to use one of the following safe methods of contraception: intra-uterine device or hormonal contraception in combination with a mechanical method of contraception.

see Link: clinicaltrials.gov/NCT04931368

Study Test Center	PI / SC	Phone	E-Mail
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Universitäres Cancer Center HAMBURG
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Pilot-trial of Methotrexate, Tafasitamab (Minjuvi®), Lenalidomide (Revlimid®) and Rituximab in patients ineligible for HCT-ASCT with Primary Central Nervous System Lymphoma (PCNSL)

Recruitment Status: RECRUITING

Condition: Non-Hodgkin Lymphoma/ Central Nervous System Lymphoma (PCNSL)
Primary Completion Date: 2027-02
Intervention/ Treatment: DRUG: **Tafasitamab/ Lenalidomide/ Rituximab/ Methotrexate**

Inclusion Criteria:

Age 18-69 years with ECOG PS ≥2 or age ≥70 years, and ineligible for HCT-ASCT as per investigators discretion /
Previously untreated, histologically (or cytologically) confirmed diagnosis of primary B-cell lymphoma of the central nervous system (PCNSL) by local pathologist. Diagnostic sample obtained by stereotactic or surgical biopsy, CSF cytology examination or vitrectomy / At least one measurable lesion / **Adequate organ function:** Adequate **kidney function**, defined as: Serum creatinine estimated glomerular filtration rate (MDRD) ≥ 60 ml/min / Adequate **hepatic** function, defined as: ALAT and ASAT ≤ 3 ULN / Bilirubin ≤ 2.0 mg/dl (except for Meulengracht disease) / Adequate **bone marrow functio**n, defined as: White blood cell (WBC) count ≥ 3000/µL or absolute neutrophil count (ANC) ≥ 1000/µL / Platelets ≥ 50.000/µL / Hemoglobin > 8.0 g/dl / Adequate **cardiac function**, defined as: Cardiac ejection fraction ≥ 40% / Adequate **pulmonary function** as per investigators discretion / Written, signed, and dated informed consent for the trial provided by the participant / Female persons are eligible to participate if they are post-menopausal or females of no childbearing potential. / Male persons with female partners of childbearing potential are eligible to participate if they agree to contraceptive methods as described in Section 12.1.2.2.

Exclusion Criteria:

Prior treatment for PCNSL with the exception of a pre-phase treatment comprising steroid treatment and / or single application of rituximab 375 mg/m2 and methotrexate 3.5 g/m2 /
Systemic lymphoma manifestation outside the CNS / Diagnosis of previous Non-Hodgkin lymphoma at any time / Primary vitreoretinal or leptomeningeal lymphoma without manifestation in the brain parenchyma or spinal cord / HIV infection of any stage as determined by presence of anti-HIV antibodies (confirmatory test) and / or presence of RNA confirmed by PCR / Previous or concurrent malignancies with the following exceptions: / Surgically cured carcinoma in-situ / Other kinds of cancer without evidence of disease for at least 5 years / Hypersensitivity to study treatment or any component of the formulation / Stomatitis or gastrointestinal ulcerations preventing the use of methotrexate / Hepatitis B, hepatitis C or hepatitis E infection as determined by PCR / Severe active infection / Congenital or acquired immunodeficiency including previous organ transplantation / Pregnant or nursing (lactating) women. / Lack of accountability and inability to appreciate the nature, meaning and consequences of the trial and to formulate their own wishes correspondingly / Non-compliance, for reasons including, but not limited to the following: Increased alcohol consumption, drug dependency or substance abuse that would interfere with cooperation with requirements of the trial / Refusal of blood products during treatment / Any similar circumstances that appear to make protocol treatment or long-term follow-up impossible / Relationship of dependence or employer-employee relationship to the sponsor or the investigator

see Link:

clinicaltrials.gov/NCT05583071

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Universitäres Cancer Center HAMBURG

Universitätsklinikum Hamburg-Eppendorf

Age-adapted high-dose chemotherapy followed by autologous stem cell transplantation or conventional chemotherapy with R-MP as first-line treatment in elderly patients with primary CNS lymphoma - a randomized phase III study

Recruitment Status: RECRUITING

Condition: Disease of the (C) Blood and lymphatic diseases (C15)
Primary Completion Date: /
Intervention/ Treatment: DRUG: **R-MTX (Rituximab 375 mg/m² i.v. d0; MTX 3.5 g/m² i.v. d1)**

Inclusion Criteria:
immunocompetent patients with a first diagnosis of primary diffuse large B-cell lymphoma (DLBCL) of the central nervous system. / age > 70 years or age 65-70 years, if not suitable for more intensive therapy (e.g. OptiMATe study). / histologically or cytologically confirmed diagnosis of diffuse large B-cell lymphoma (according to the findings of the pathologist at the center). / diagnostic sample by stereotactic or surgical biopsy, CSF cytology or vitrectomy. / disease localized exclusively in the CNS. / presence of at least 1 measurable lesion. / ECOG performance status ≤2. / Patients considered to be high-dose capable, in the opinion of the treating physician. / written informed consent of the patient or, in case of temporary incapacity of the patient due to his/her illness, of a court-appointed health care representative in accordance with international guidelines and local legislation / **additional randomization criteria:** patients considered high-dose-capable (fit for HDT-ASCT), defined by EBL score (only one or none of the 3 criteria may apply: ECOG PS > 1, Barthel Index (ADL) < 20 und Lachs geriatrisches Screening > 3), improvement of ECOG PS after pre-phase therapy or decision of the treating physician after discussion with the study expert team. 2. no evidence of disease progression after pre-phase therapy.

Exclusion Criteria:
Congenital or acquired immunodeficiency (e.g. HIV infection or previous organ transplantation). / systemic lymphoma manifestation (outside the CNS). / primary vitreoretinal lymphoma or primary leptomeningeal lymphoma without manifestation in the CNS parenchyma or spinal cord. / previous or concurrent other cancer with the exception of surgically cured carcinoma in situ or other cancer in complete remission for at least 5 years. / previous systemic non-Hodgkin's lymphoma. / inadequate renal function (creatinine clearance <60 ml/min). / inadequate bone marrow, heart, lung or liver function as assessed by the investigator. / active hepatitis B or C disease. / concurrent therapy with experimental drugs or participation in a clinical trial with receipt of study medication within the last 30 days prior to initiation of therapy. / clinically relevant fluid accumulation (“third space”) as assessed by the investigator. / known hypersensitivity to any of the study drugs or their ingredients. / taking medication that is likely to interact with the study medication. / known or persistent medication, drug or alcohol abuse. / active COVID-19 infection or non-compliance with the currently valid hygiene / non-consenting patients who are unable to understand the nature, significance or consequences of the study and who do not have a court-appointed health care proxy. / previous participation in this study. / individuals who have a relationship/dependent relationship with the sponsor and/or investigator. / any family, sociological or geographical conditions that have the potential to interfere with compliance with the study protocol or follow-up. / fertile patients who refuse to use safe methods of contraception during the study.

see Link: Drks.de:DRKS00024085

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Palliative studies

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Improvement of Quality of Life by Cannabinoids in Oncologic Patients

Recruitment Status: RECRUITING

Condition: Medical Oncology/ Palliative Care/ Quality of Life/ Cannabinoids
Primary Completion Date: 2026-11-30
Intervention/ Treatment: DRUG: **Cannabisextrakt Avextra 10/10 Lösung**

Inclusion Criteria:
≥25 years old and legally competent / Palliative oncological therapy / ECOG status 1, 2 or 3, incapacitated for work / ESAS TSDS > or equals 16 / Nutritional Risk Screening > or equals 3 / Pain numerical rating scale > or equals 4 / informed consent / **for WOCBP**: Negative pregnancy test / Reliable contraception (Pearl Index < 1%)

Exclusion Criteria:
nausea > or equals grade 3 (CTCAE) or vomiting > or equals grade 2 (CTCAE) in the preceding week / Inability to understand and complete the questionnaires / Cannabis use in the last 6 weeks / Alcohol addiction / Pregnancy/lactation / Contraindications or intolerance to the study medication (esp. psychosis) / Simultaneous participation in other clinical studies (sumulataneous participation in non-interventional studies (i.e. biomarker-studies, registries) is allowed, if the study-aim does not interfere with measures of the second study) / Any other condition as judged by the investigator, e.g. non-compliance

see Link:

clinicaltrials.gov/NCT06097533

Study Test Center	PI / SC	Phone	E-Mail
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