

Solid tumors I		Solid tumors II		Haematological diseases	
1	<a href="#">Bronchial cancer / Lung</a>	13	<a href="#">Gynaecological tumors</a>	25	<a href="#">Leukemias</a>
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3	<a href="#">Esophageal cancer</a>	15	<a href="#">Sarcomas</a>	27	<a href="#">Mastocytosis</a>
4	<a href="#">Gastric cancer and gastro-Esophageal junction</a>	16	<a href="#">Hepatocellular cancer</a>	28	<a href="#">Hodgkin's disease</a>
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7	<a href="#">Small bowel cancer</a>	19	<a href="#">Brain tumors</a>	31	<a href="#">Myelodysplastic syndrome (MDS)</a>
8	<a href="#">Colorectal cancer/ colon</a>	20	<a href="#">GIST tumors</a>	32	<a href="#">Anemia</a>
9	<a href="#">Urothelial bladder cancer</a>	21	<a href="#">Side effects of oncological therapies</a>	33	<a href="#">Immune thrombocytopenia (ITP)</a>
10	<a href="#">Prostate cancer</a>	22	<a href="#">Paediatric Oncology &amp; Hematology</a>	34	<a href="#">Amyloidosis</a>
11	<a href="#">Neuroendocrine tumors</a>	23	<a href="#">Cross-entity studies (Basket studies)</a>	35	<a href="#">Primary CNS lymphomas (PCNSL)</a>
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## UCC Hamburg

*This interlinked document provides you a comprehensive collection of currently recruiting interventional trials at our network.  
The links on the start page will take you to the entities with the main inclusion criteria for the individual studies (Trial Pathways path).  
Further information can be found through the provided links.*

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

***This information is intended for personal use.***

***For any suggestions, additions or corrections please contact:***

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<b>Lead clinical research</b>	PD Dr. med. MBA	Andreas Block	E-Mail: <a href="mailto:block@uke.de">block@uke.de</a>

**Quellen:**  
[clinicaltrialsregister.eu](http://clinicaltrialsregister.eu)  
[clinicaltrials.gov](http://clinicaltrials.gov)  
[Drks.de](http://Drks.de)  
[Dpcg.nl](http://Dpcg.nl)

[continue...](#) 

## 1 Trial pathways

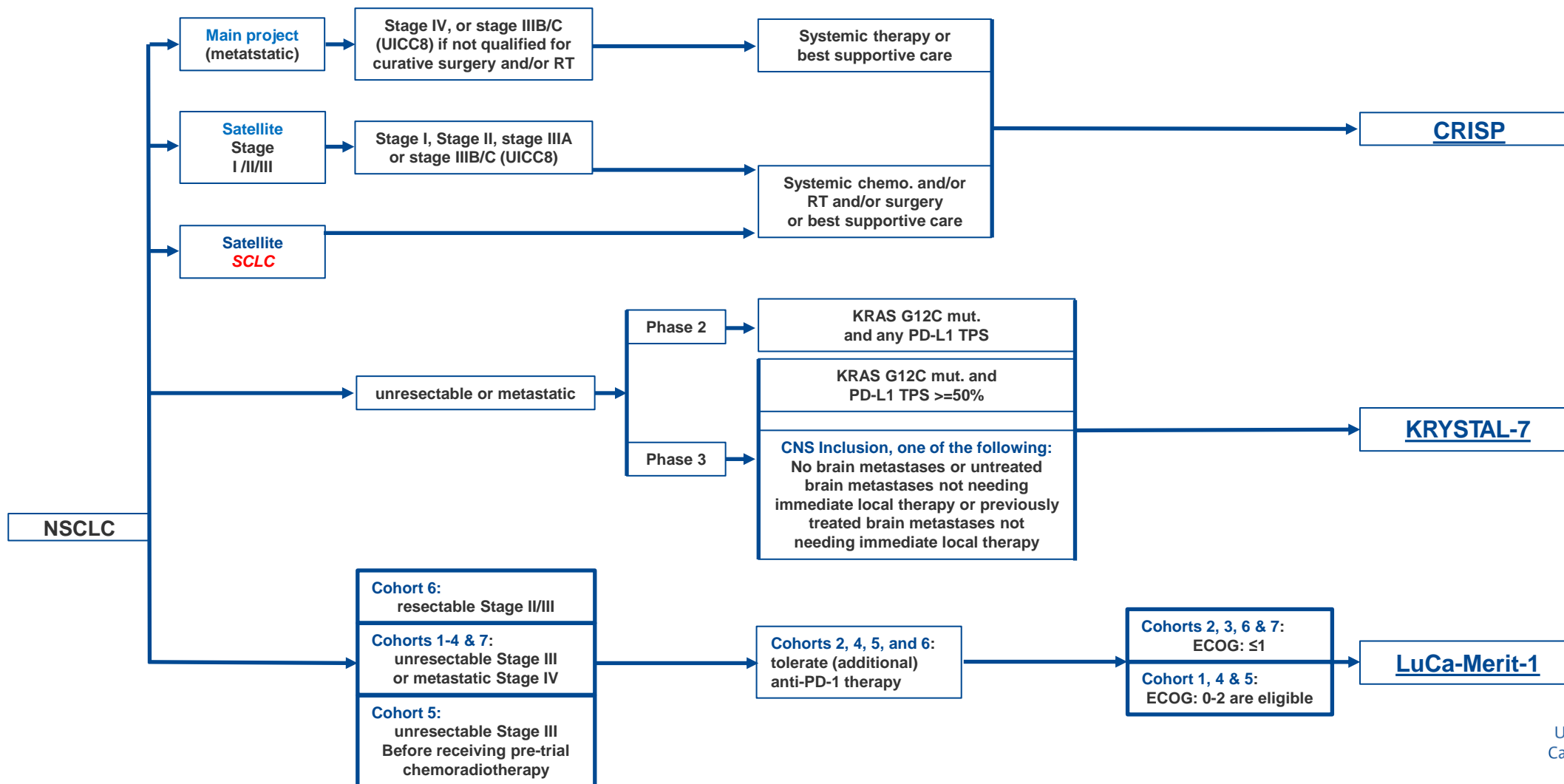
# *Bronchial cancer / Lung*

1a NSCLC

1b SCLC

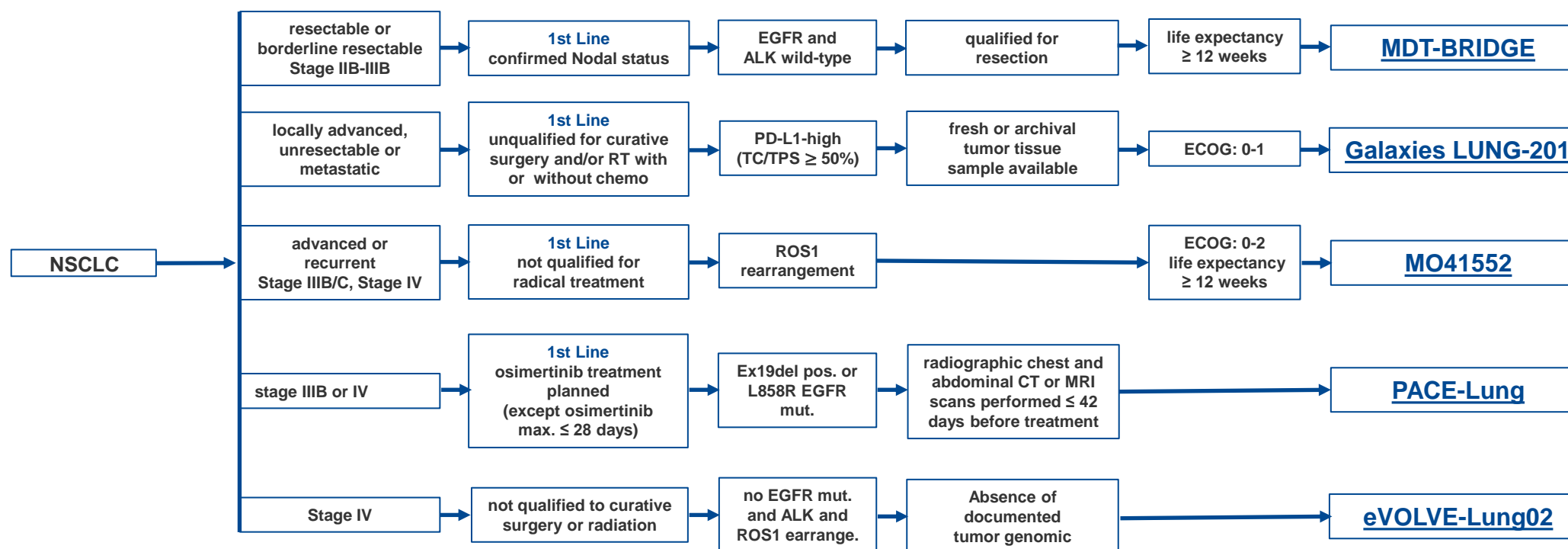
1a

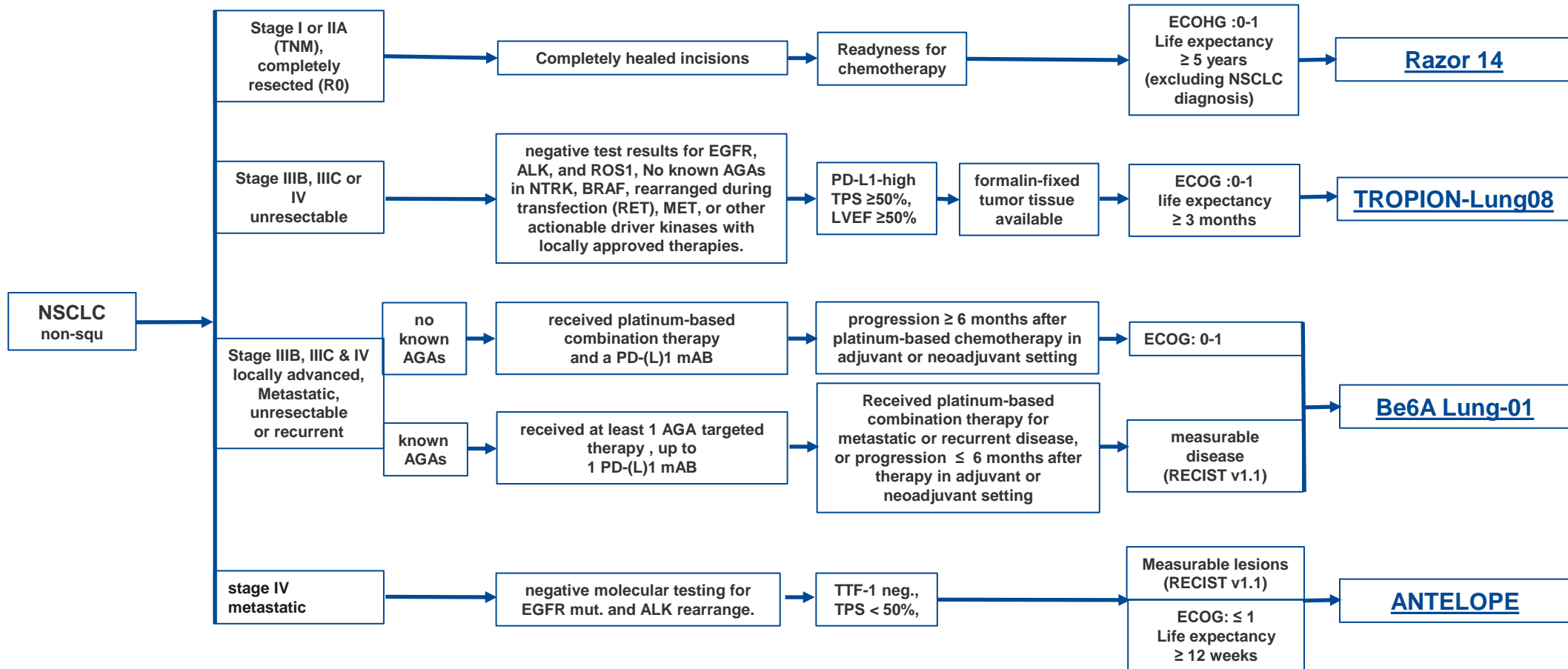
# Trial pathways / *Bronchial cancer / NSCLC*



1a

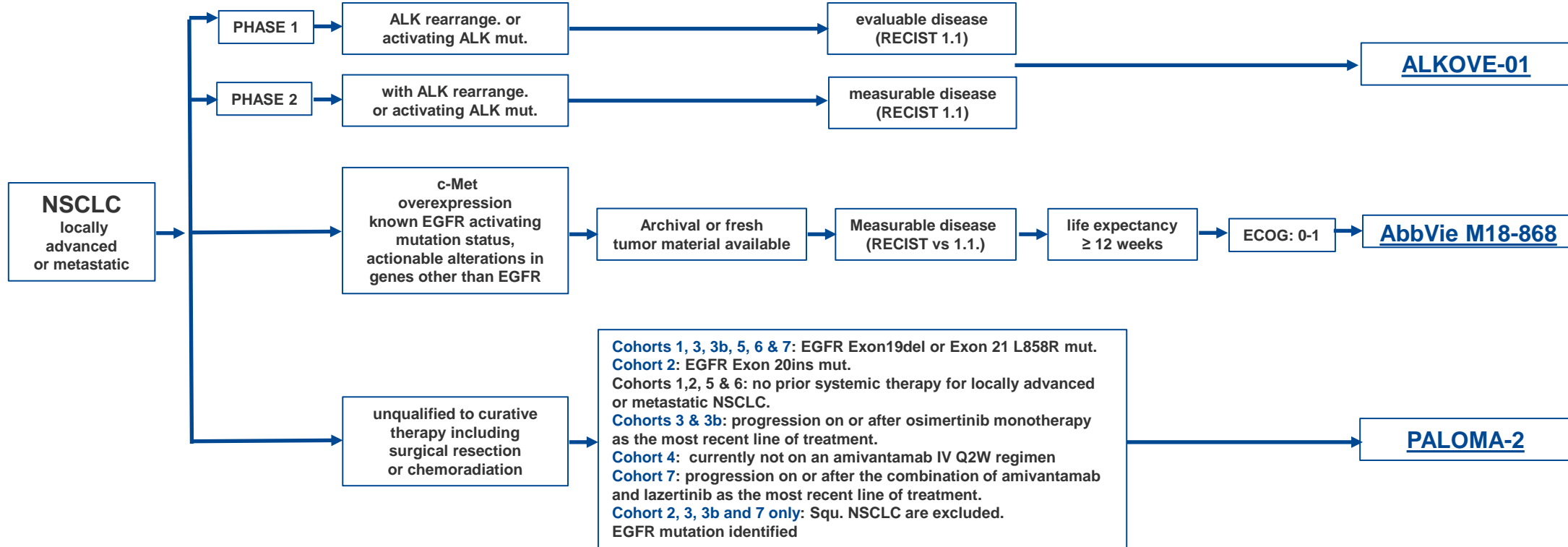
# Trial pathways / *Bronchial cancer / NSCLC*





1a

# Trial pathways / *Bronchial cancer / NSCLC*



1b

## Trial pathways / *Bronchial cancer* / SCLC

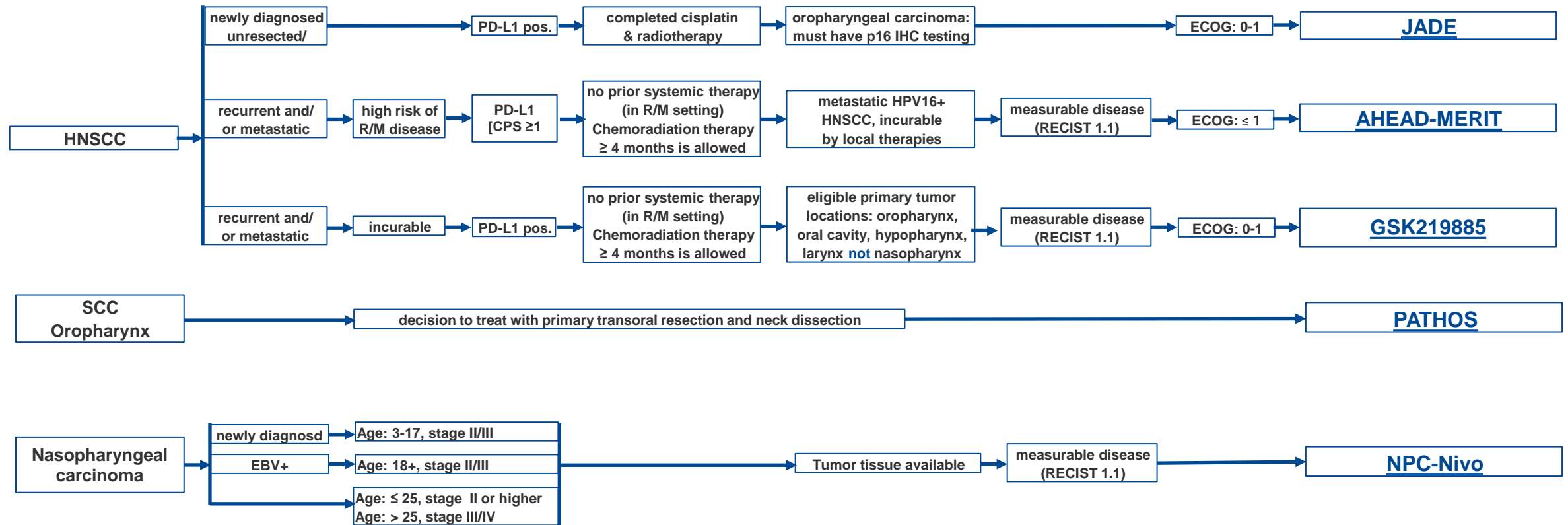


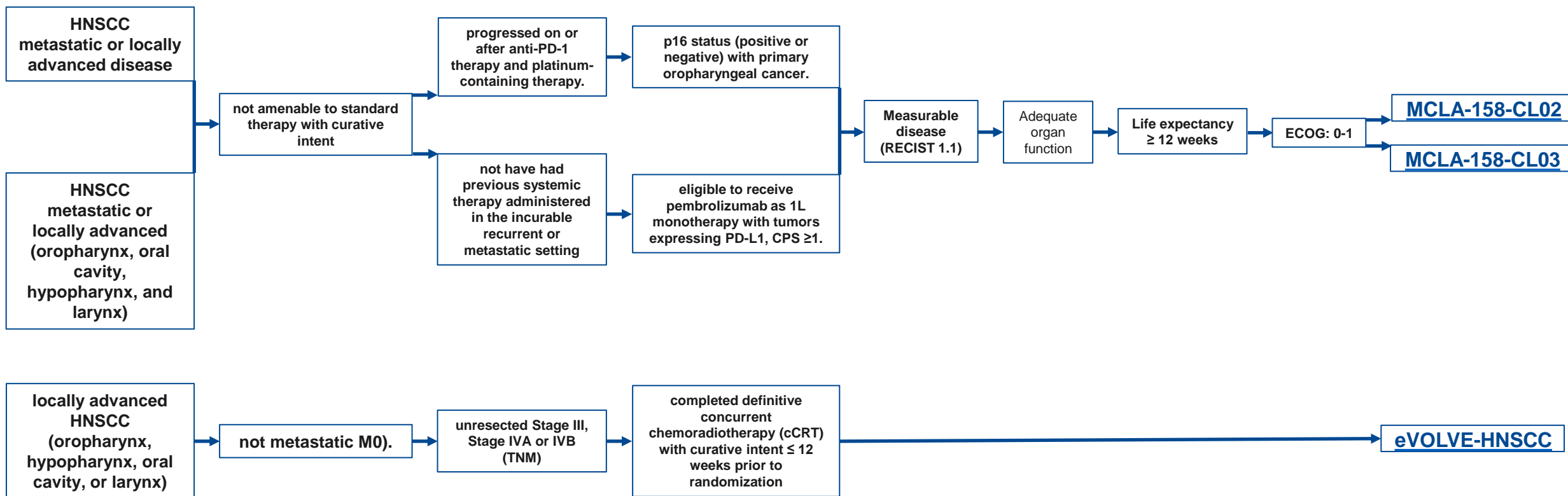
***Please also check the possibility of inclusion in the BASKET studies!***



# *Head and neck tumors*

[continue...](#) →





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

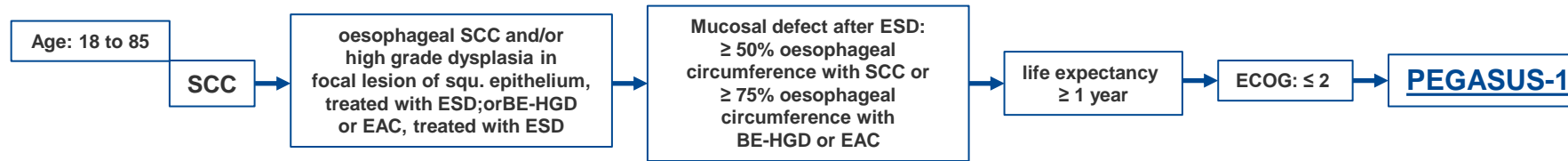
# *Esophageal cancer*

3a

Oesophagus-unresectable or metastatic

3b

Oesophagus + gastroesophageal junction - resectable





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

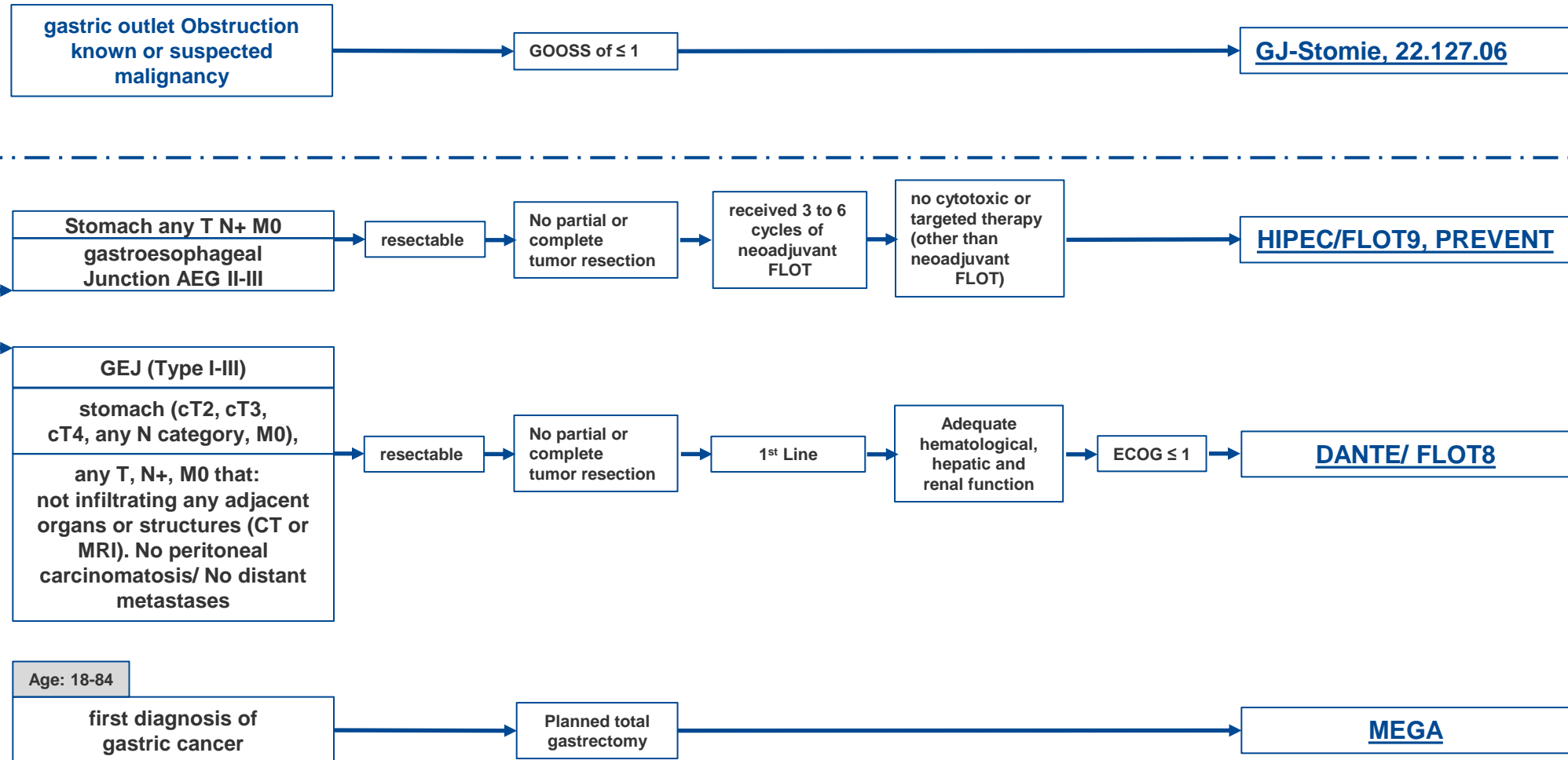
# *Gastric cancer and gastroesophageal junction*

4a

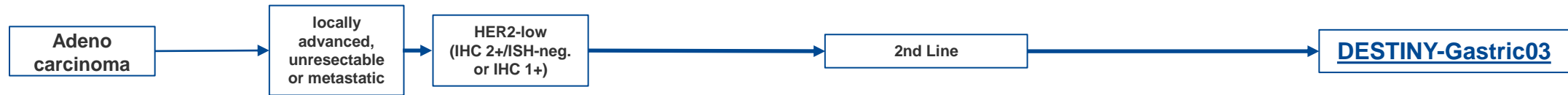
resectable

4b

unresectable

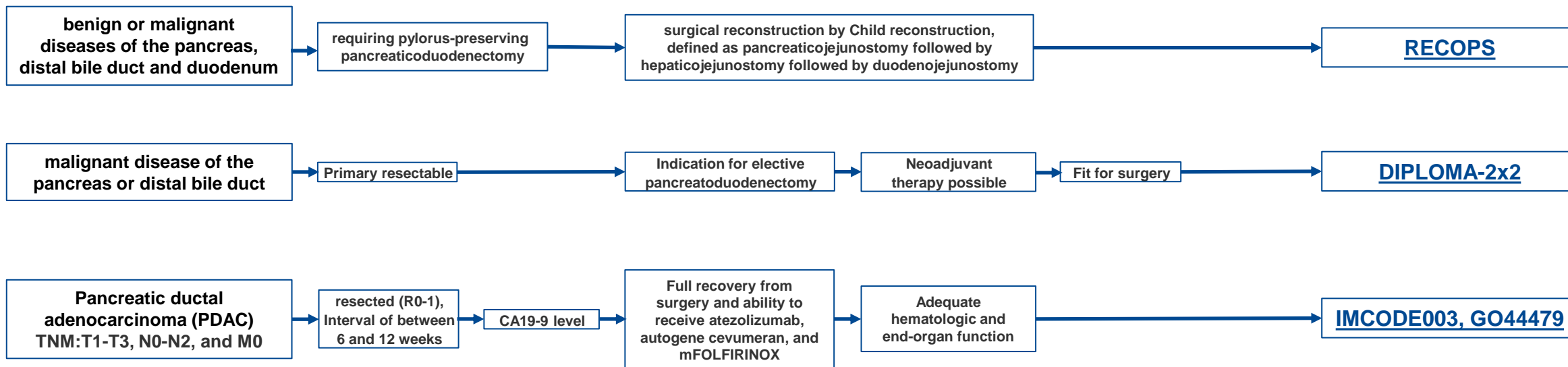


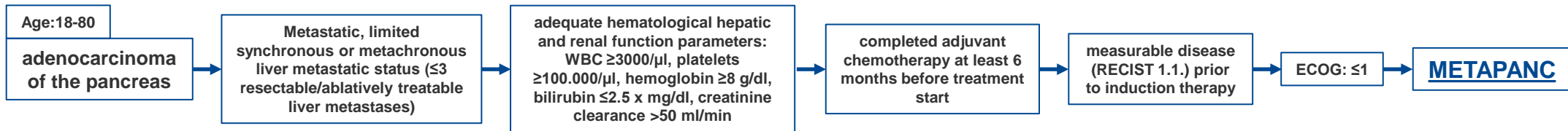




# *Pancreatic cancer*

- 5a localised
- 5b metastatic

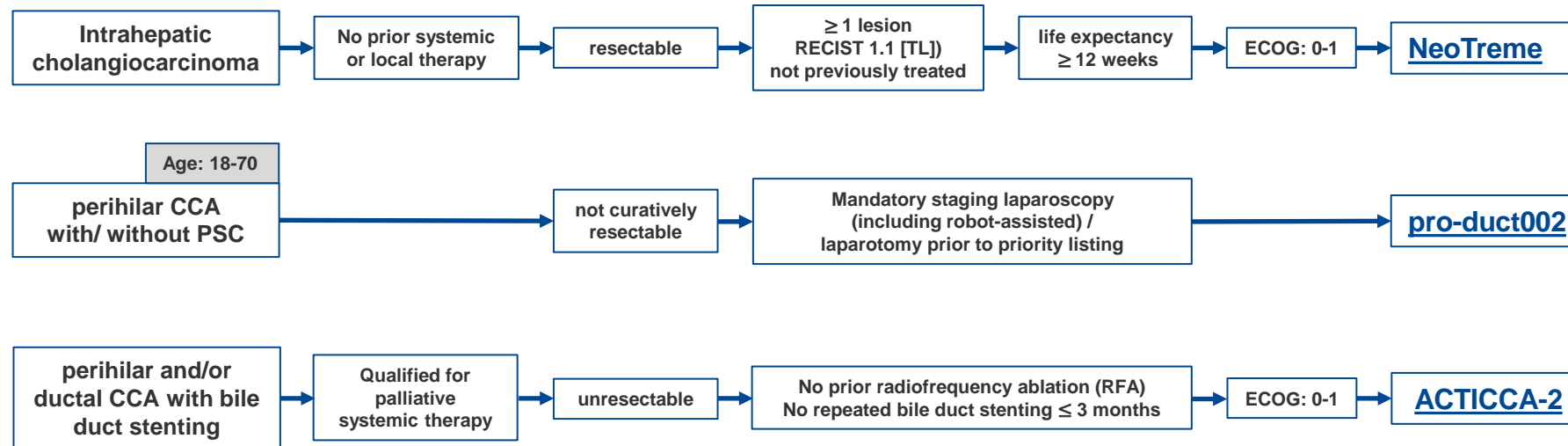




*Please also check the possibility of inclusion in the BASKET studies!*

# *Cholangiocellular carcinoma*

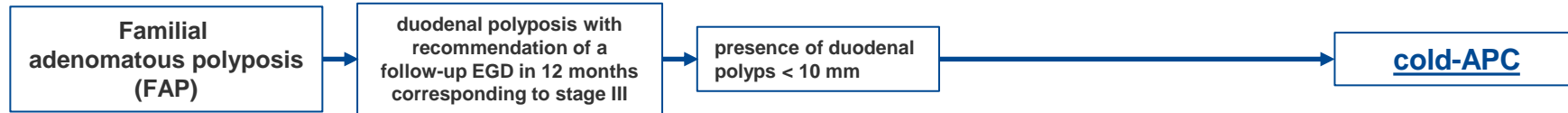
[continue...](#) →



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

# *Small bowel cancer*

[continue...](#) →



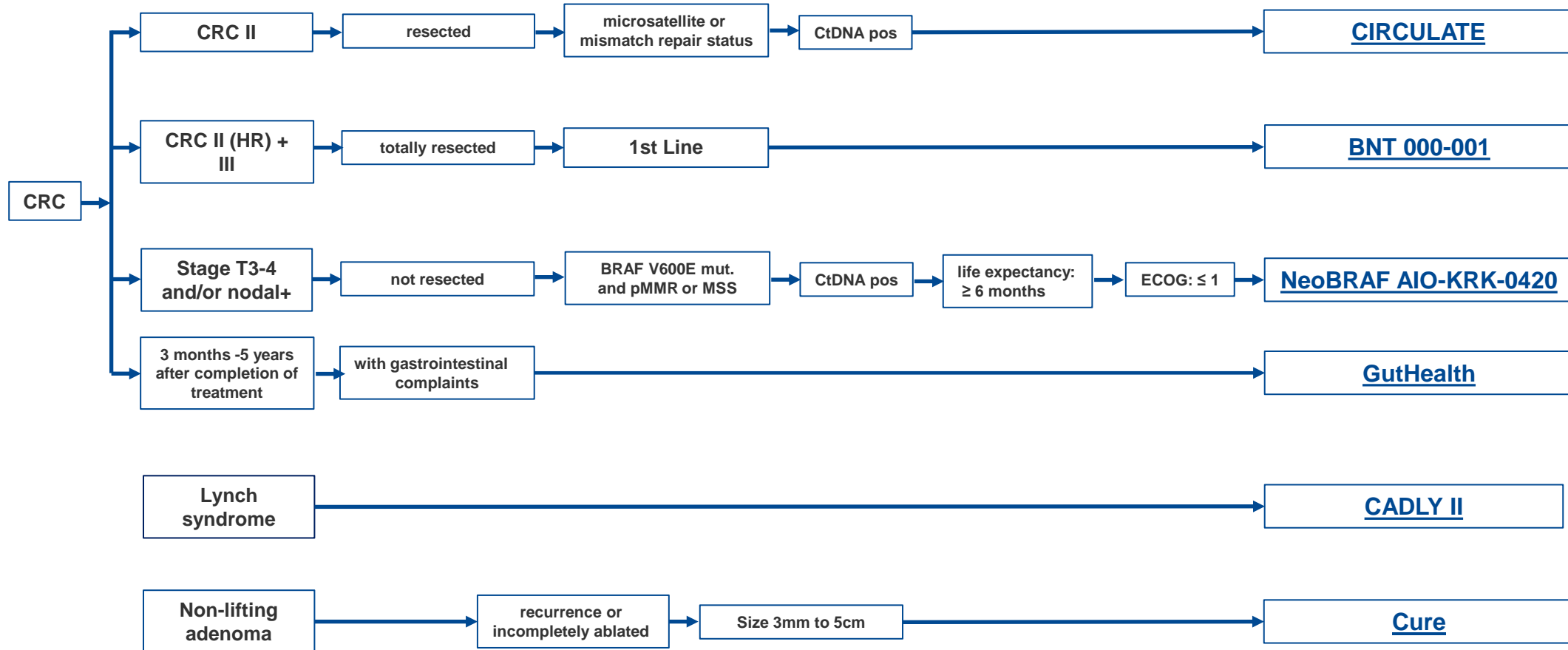
*Please also check the possibility of inclusion in the BASKET studies!*

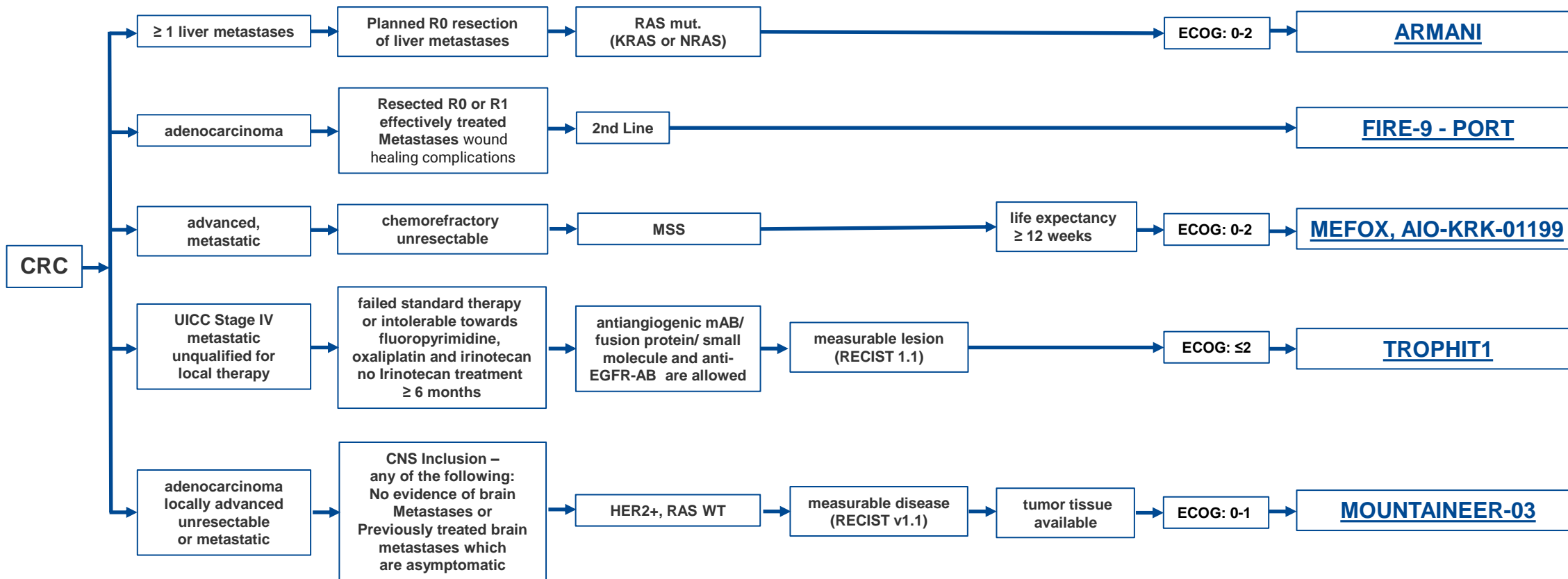


# *Colorectal cancer / colon*

8a localized

8b metastatic

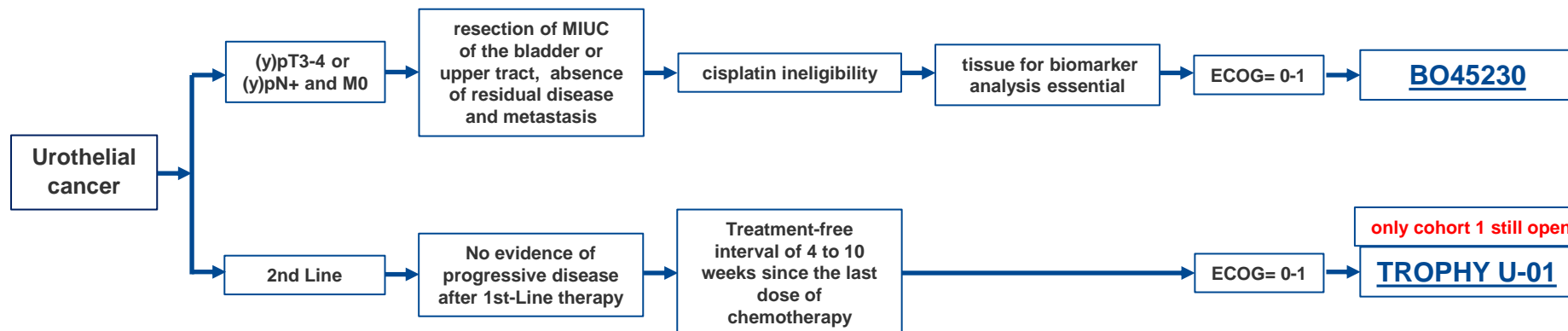




**Please also check the possibility of inclusion in the BASKET studies!**

# *Urothelial bladder cancer*

[continue...](#) →

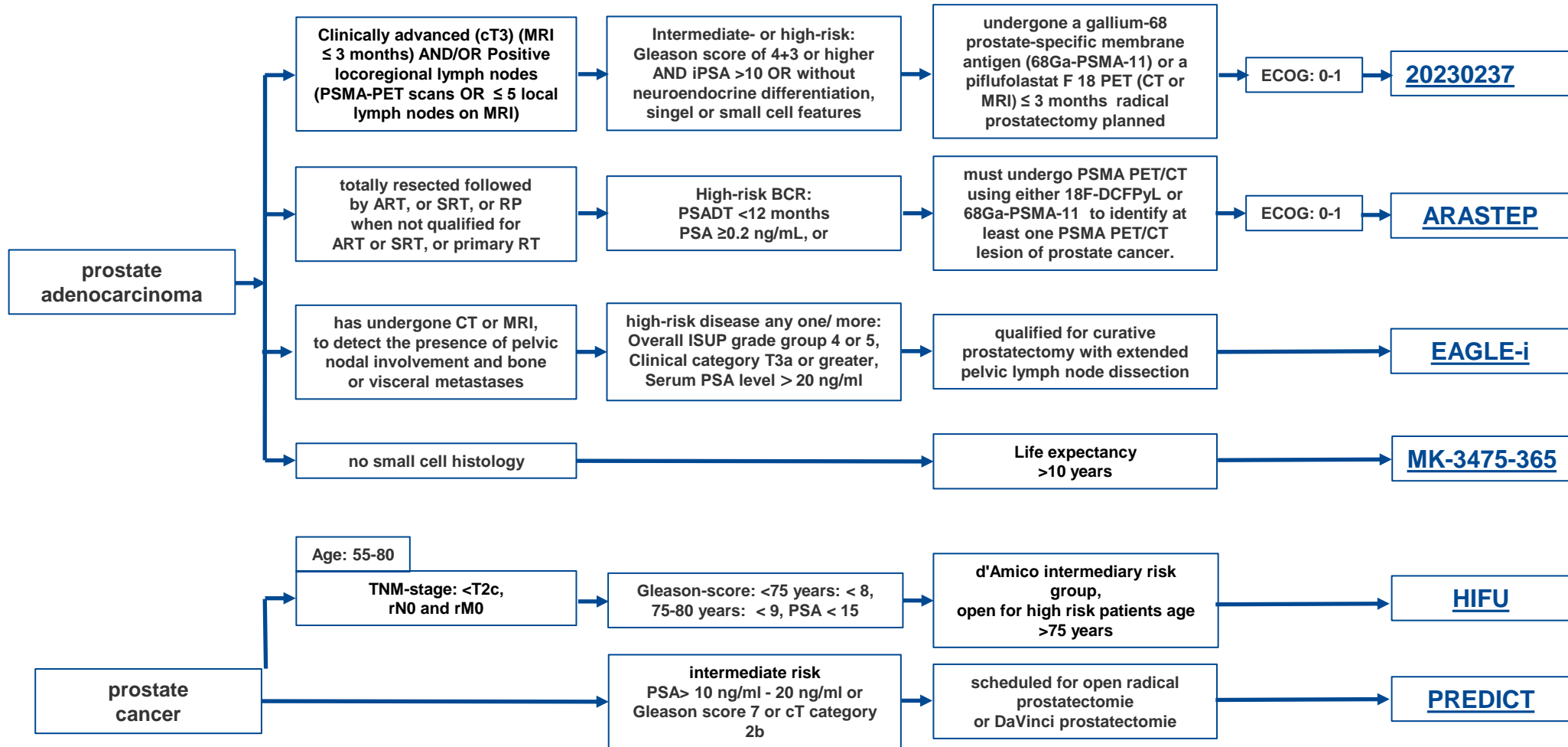


*Please also check the possibility of inclusion in the BASKET studies!*

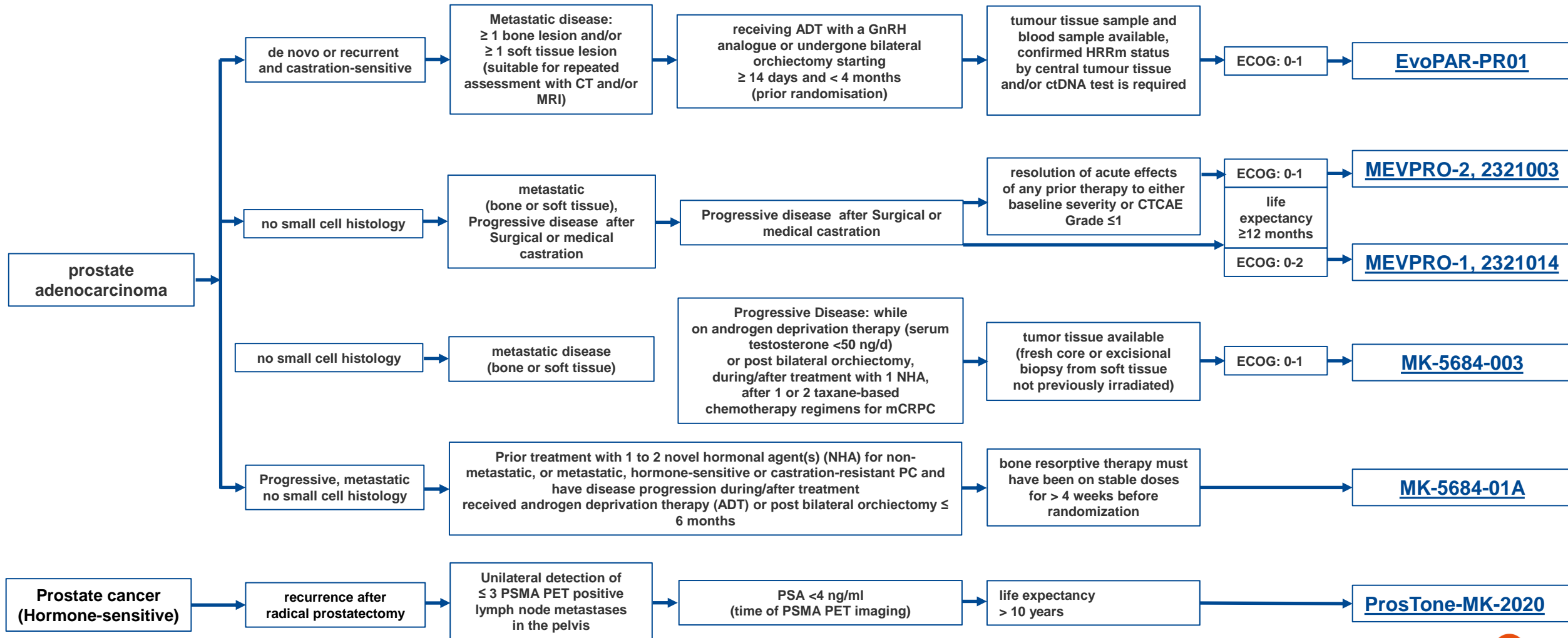
# *Prostate cancer*

- 10a localized
- 10b metastatic

## Trial pathways / *Prostate cancer (localized)*



## Trial pathways / *Prostate cancer (metastatic)*





# *Neuroendocrine tumors*

continue... →

Currently no study options

# *Breast cancer*

12a

Preventive

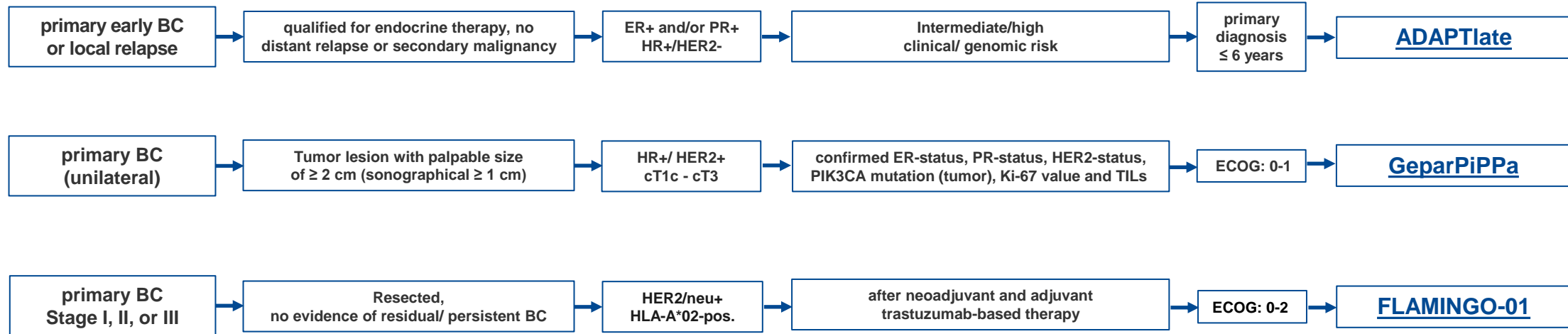
12b

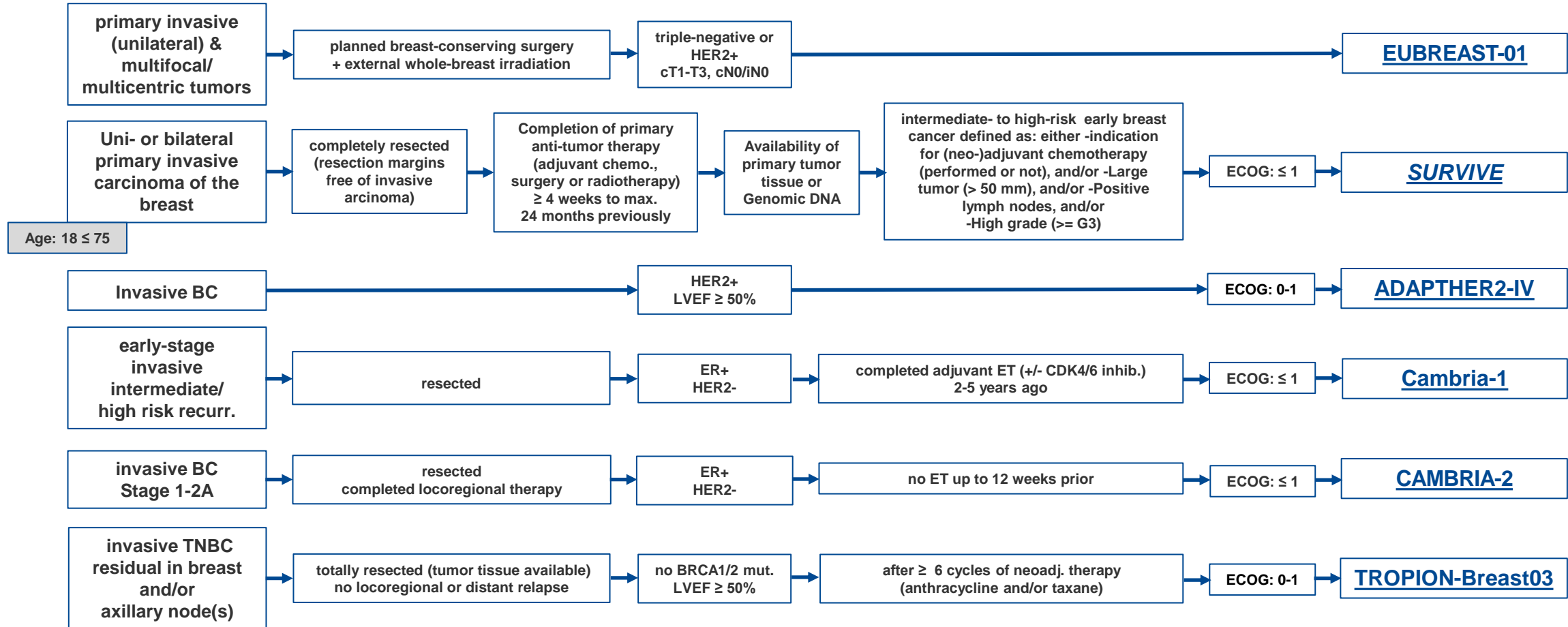
localized

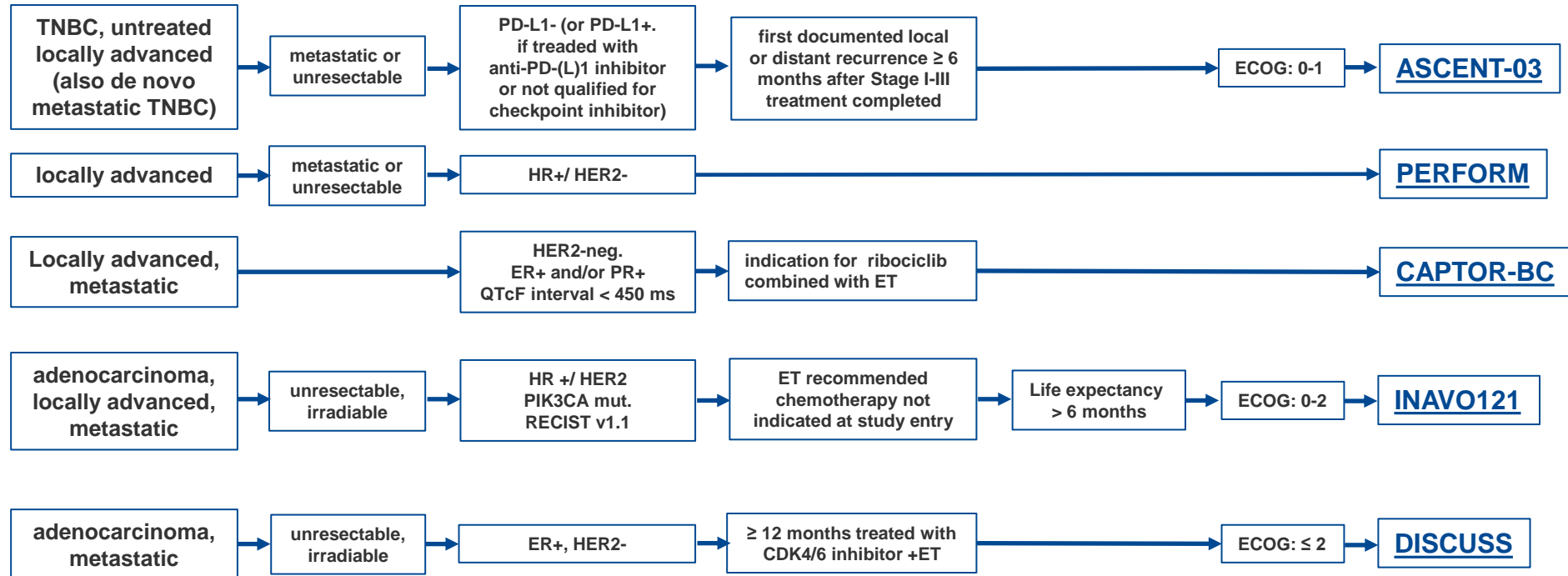
12c

metastatic









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

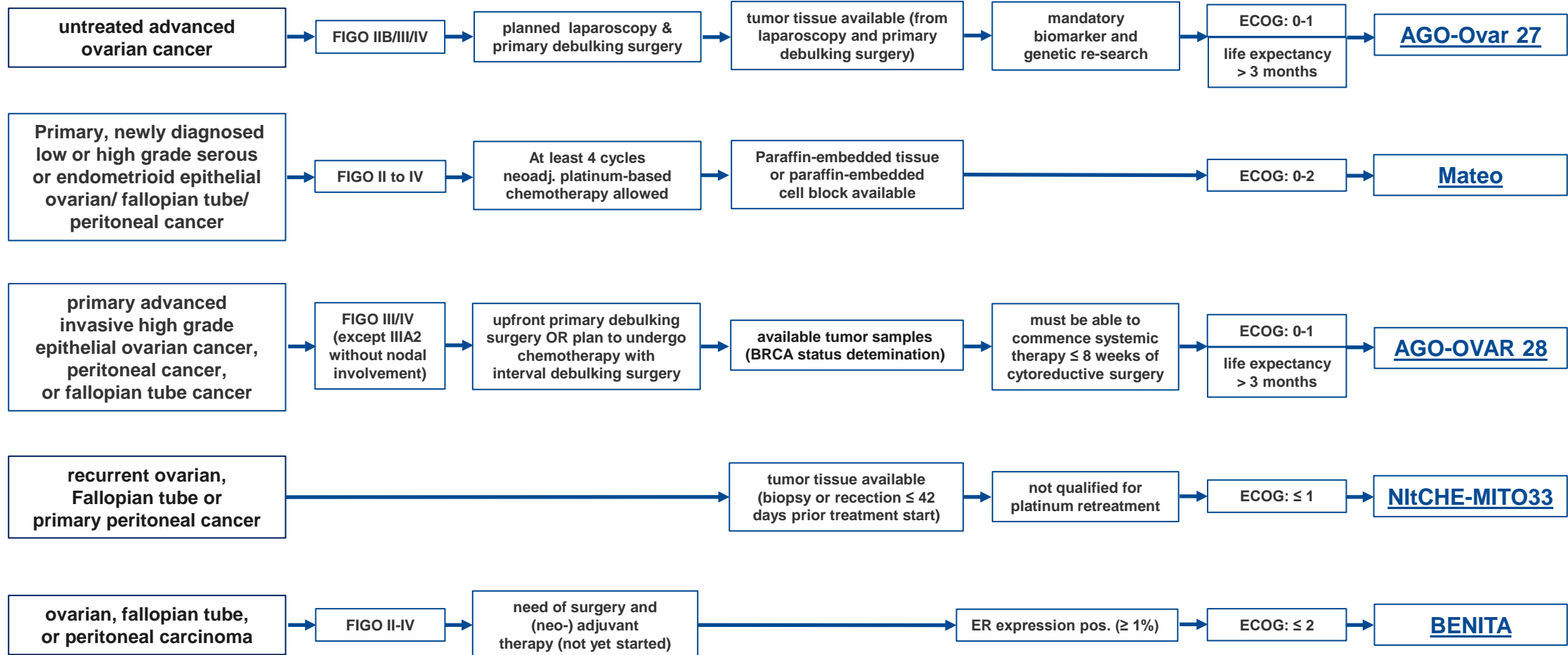
# *Gynaecological tumors*

13a Ovarian cancer

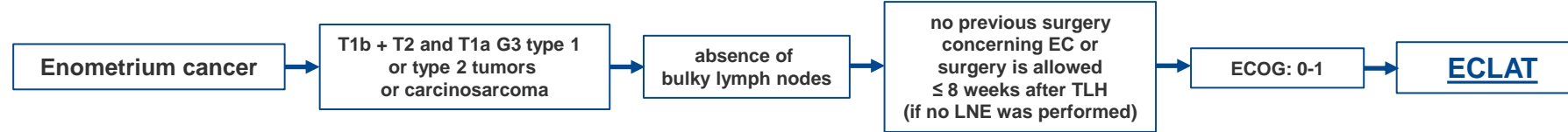
13b Cervical cancer

13c Endometrial cancer





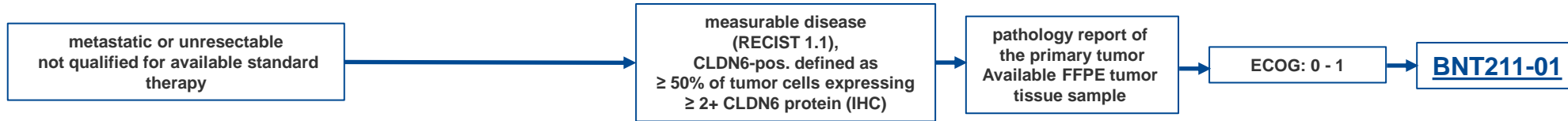
Currently no study options



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

# *Germ cell tumors*

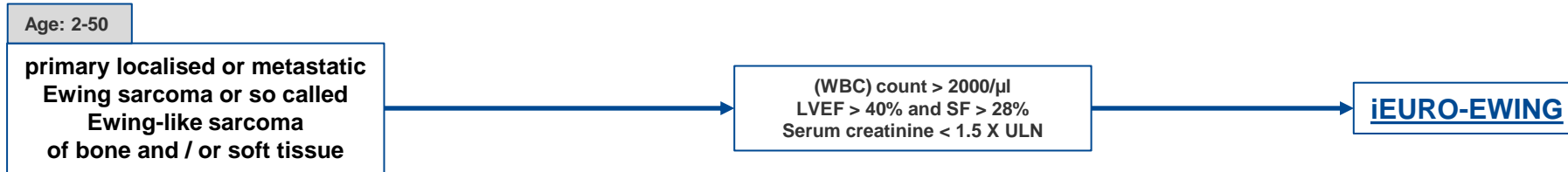
[continue...](#) →



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

# *Sarcomas*

[continue...](#) →



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

# *Hepatocellular cancer*

16a

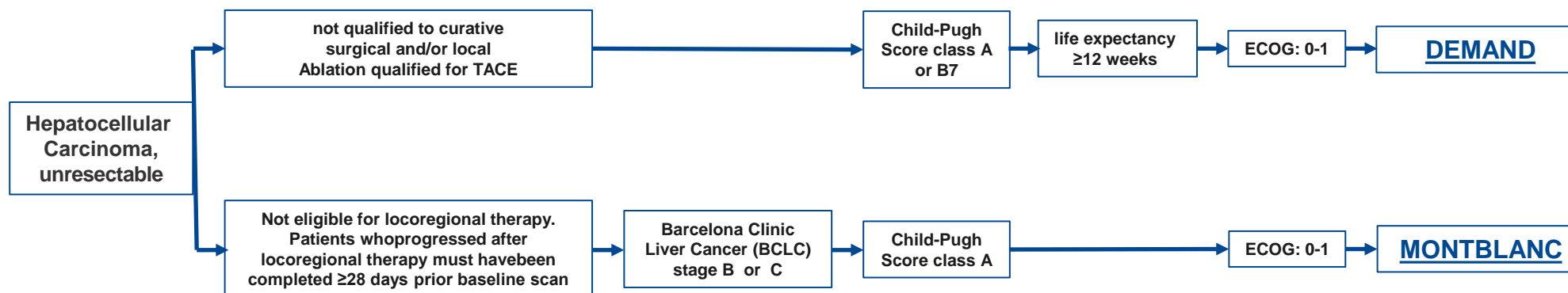
resectable

16b

unresectable



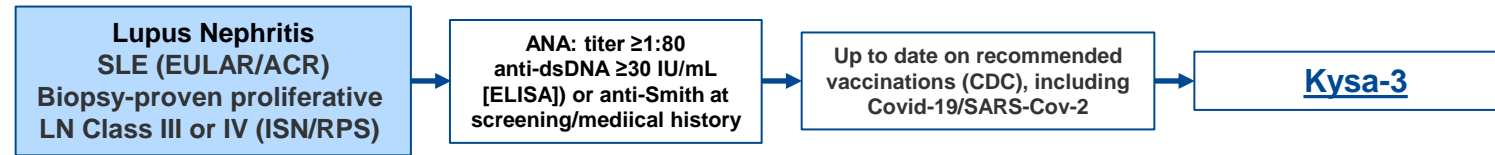
Currently no study options



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

# *Renal cell cancer*

continue... →



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

# *Skin tumors*

18a

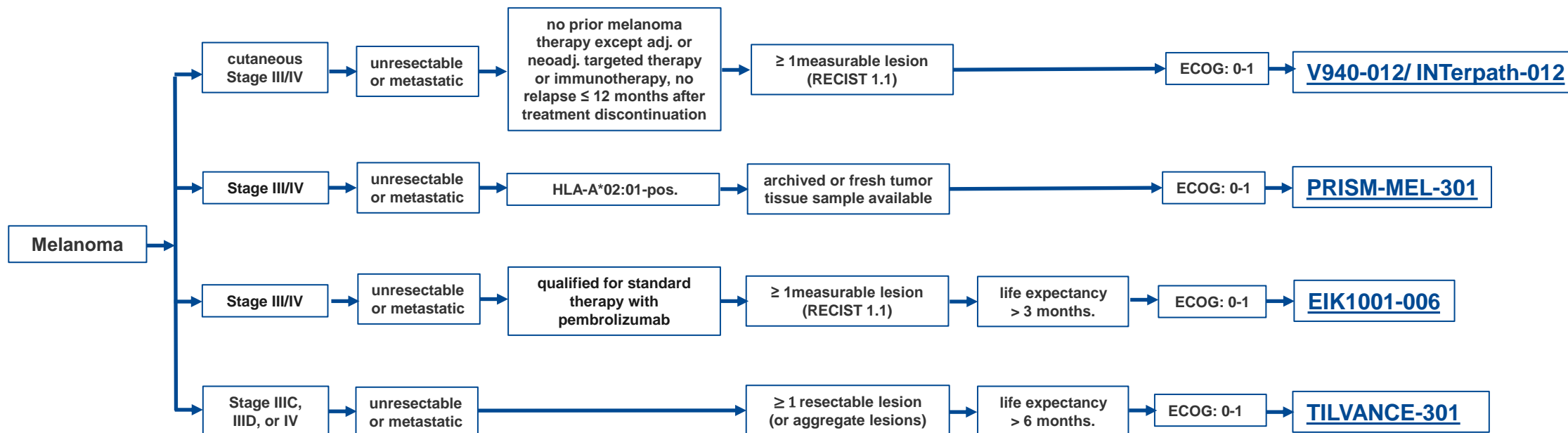
*Melanoma*

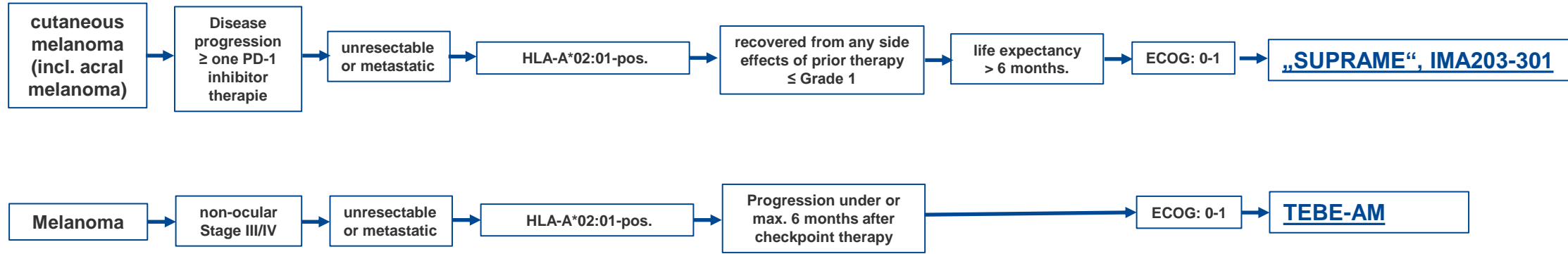
18b

*Other Neoplasms Skin*

18c

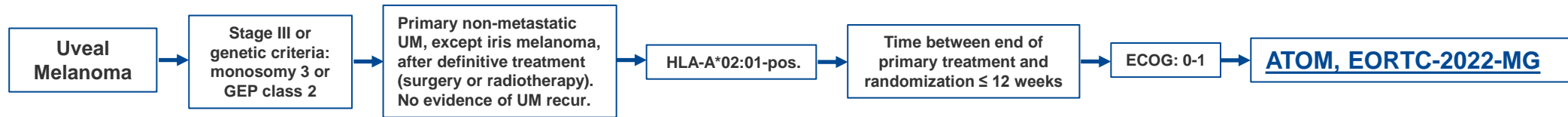
*(Uveal Melanoma)*





Currently no study options





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

# *Brain tumors*

[continue...](#) →

Currently no study options

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

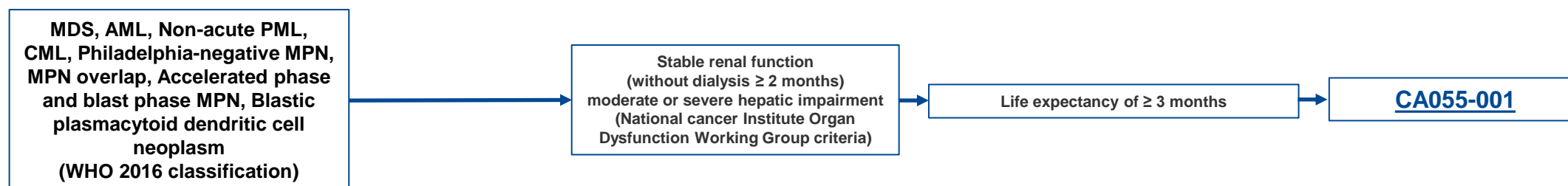
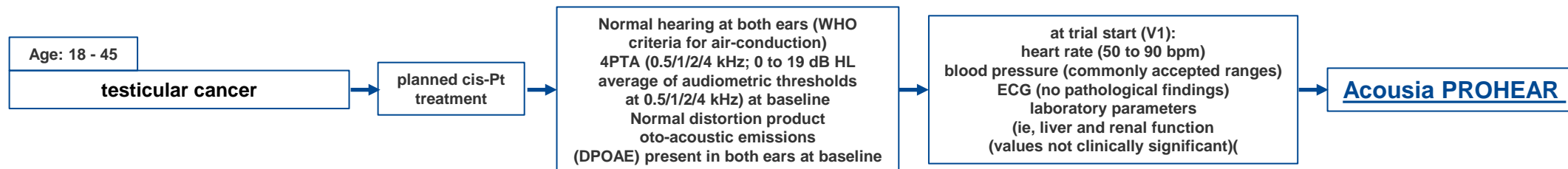
# *GIST tumors*

[continue...](#) →

Currently no study options

# *Side effects of oncological therapies*

continue... →



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

# *Paediatric Oncology & Hematology*

[continue...](#) →



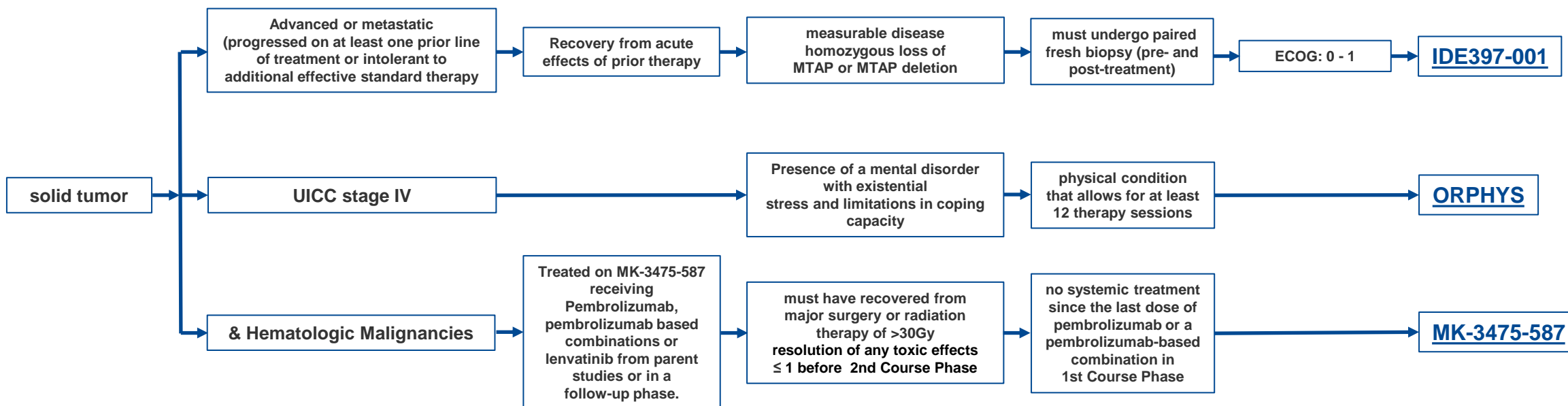
## GPO studies and register studies

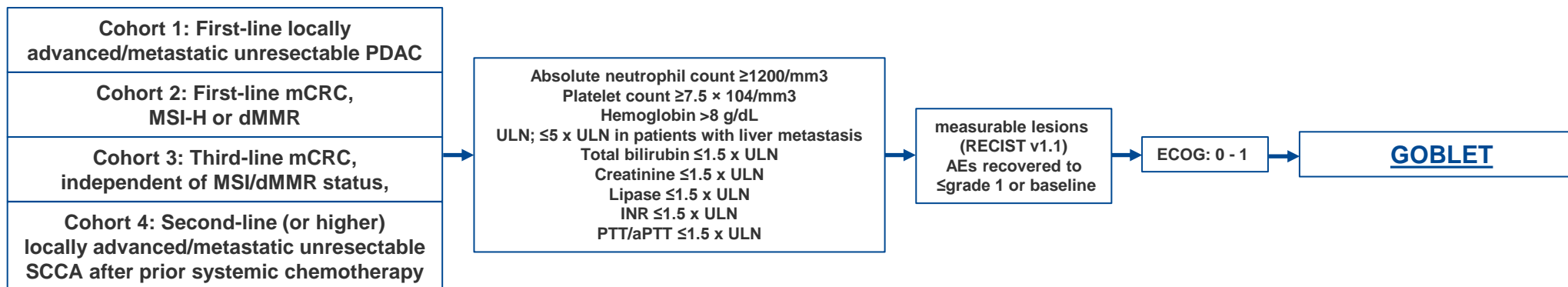
[http://www.kinderkrebsinfo.de/e1676/e9032/index\\_ger.html](http://www.kinderkrebsinfo.de/e1676/e9032/index_ger.html)

[Studienverbund Pädiatrische Hämatologie und Onkologie Nordwest – Gemeinsam für eine bessere Medizin. \(studienverbund-nordwest.de\)](http://studienverbund-nordwest.de)

# *Cross-entity studies „Basket studies“*

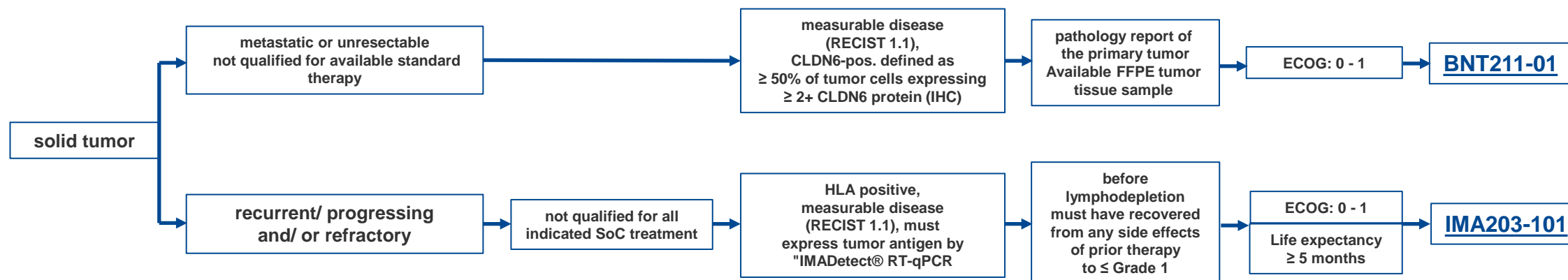
[continue...](#) →





# *Cellular Therapies*

continue... →



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

# *Leukemias*

25a

ALL

25b

AML+MDS

25c

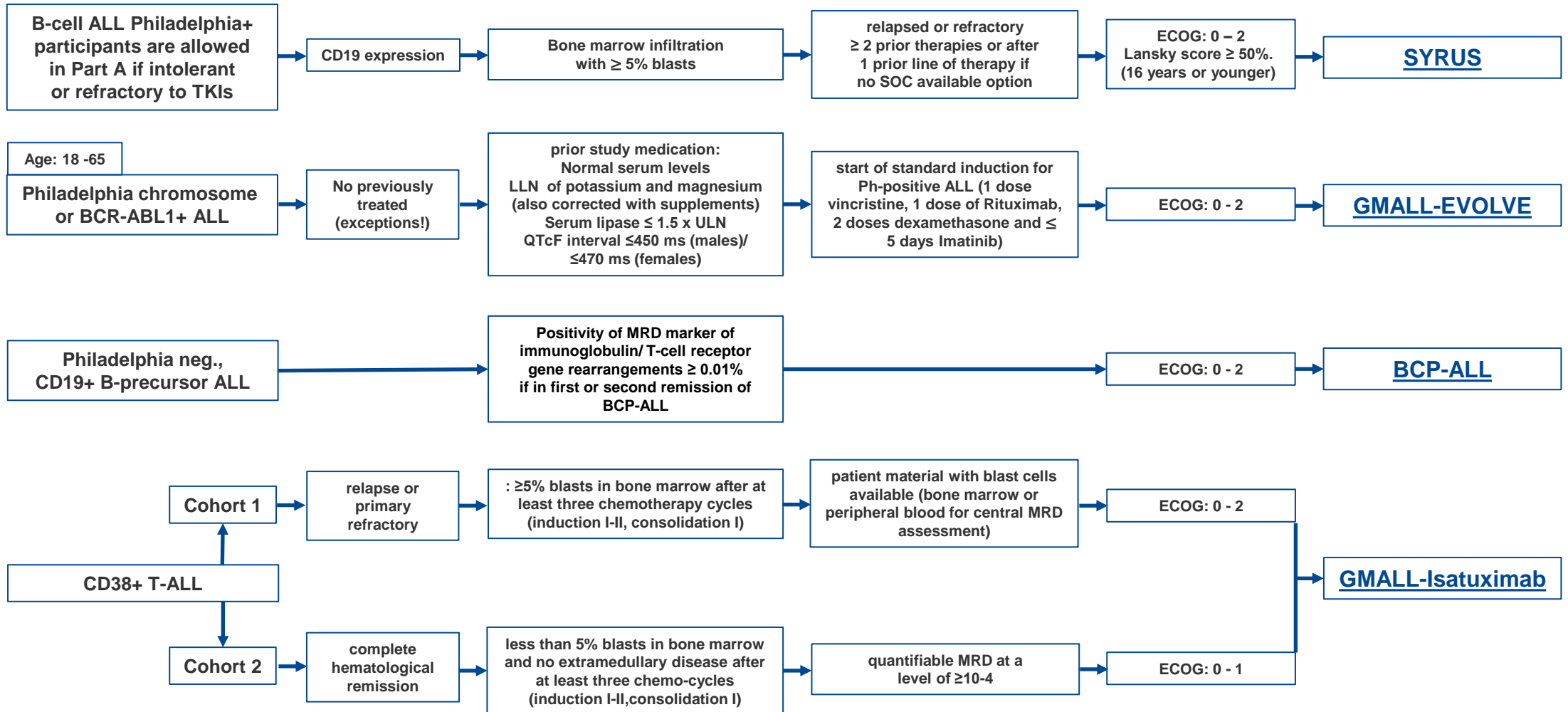
CLL

25d

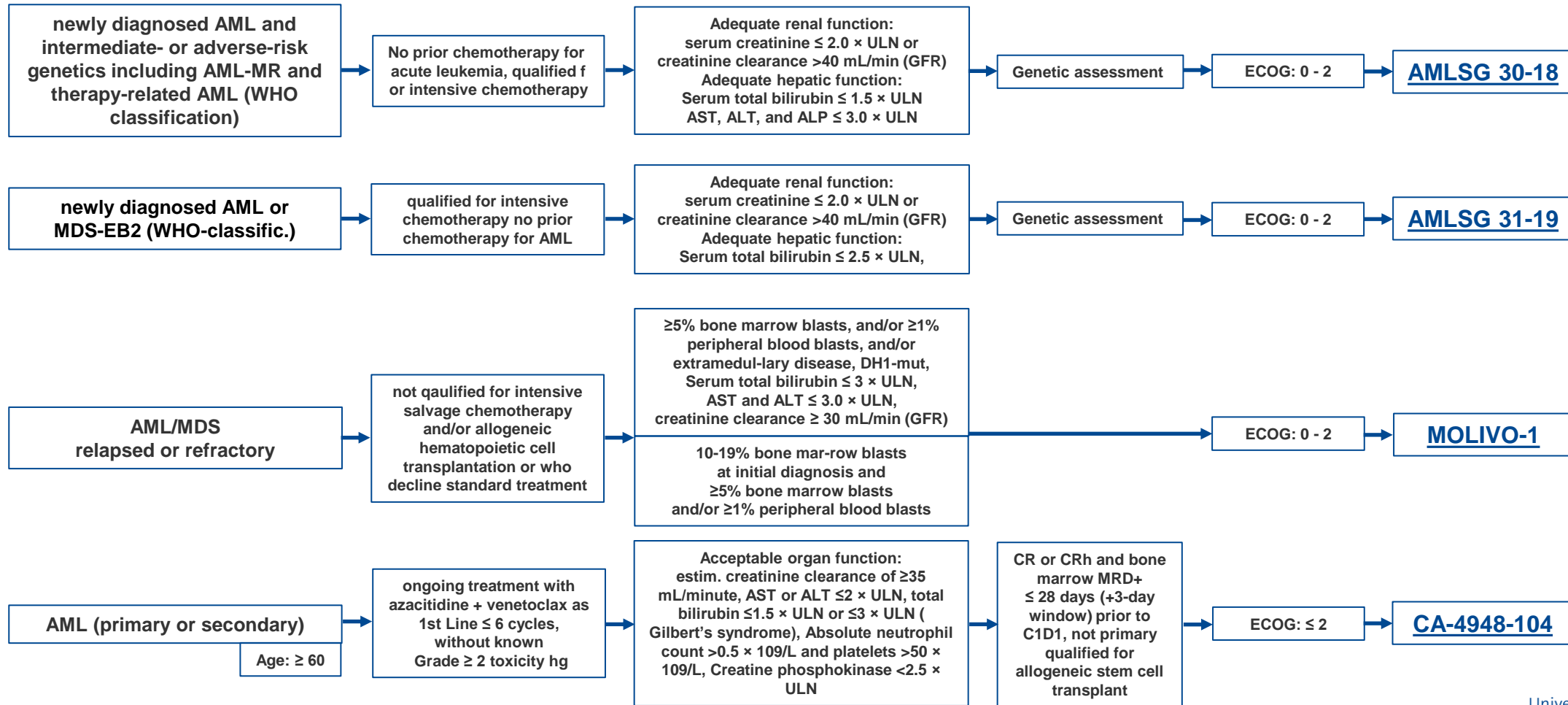
CML

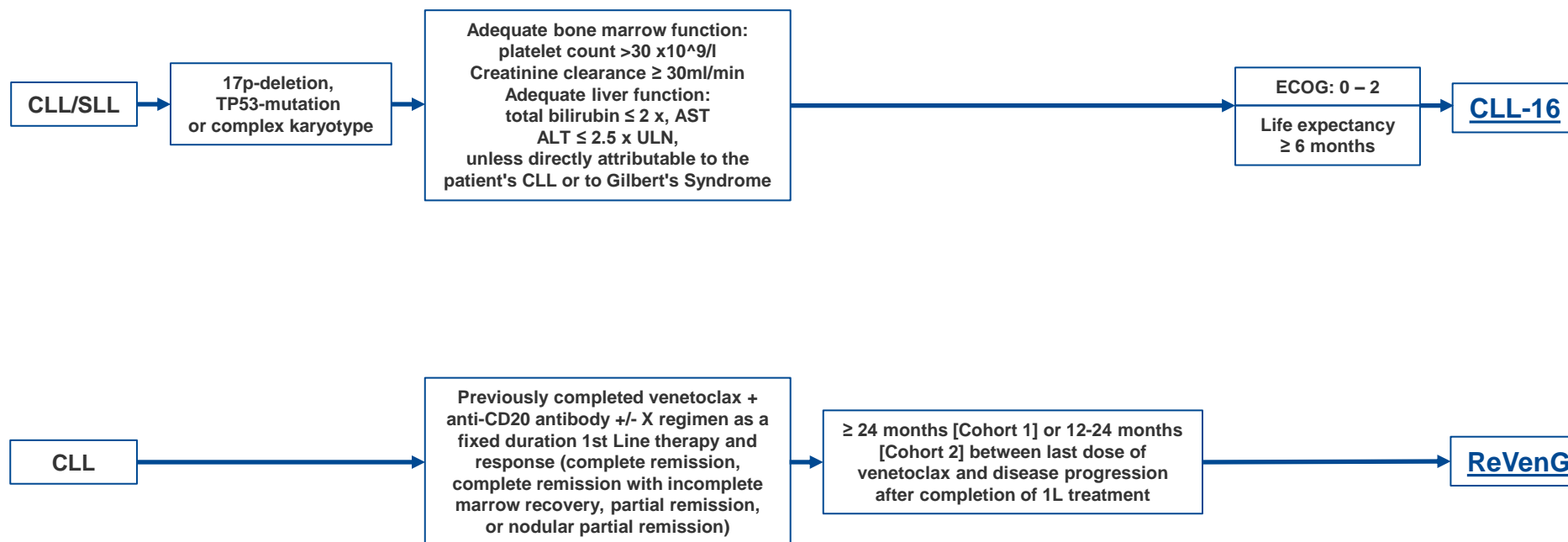
Contact at UCC Hamburg

Prof. Dr. med. Walter Fiedler, Tel. 040/ 7410 53919 (ALL & AML)  
Dr. med. Philippe Schafhausen, Tel: 040 7410-57122 (MDS & CML)  
Dr. med. Minna Voigtländer, Tel. 0152 228 179 11 (CLL)







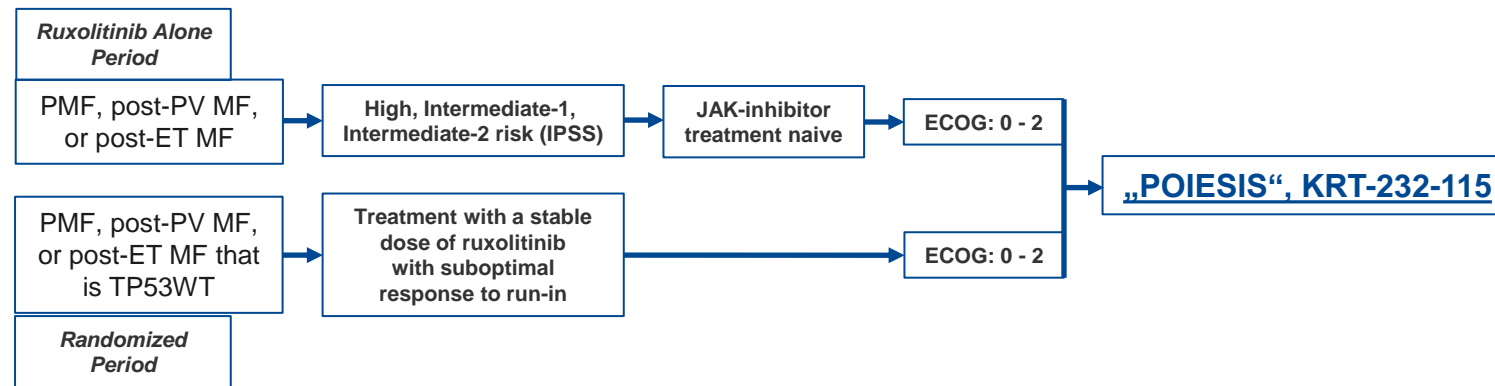


Currently no study options

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

# *Myeloproliferative neoplasms (MPN)*

[continue...](#) →



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

# *Mastocytosis*

[continue...](#) →

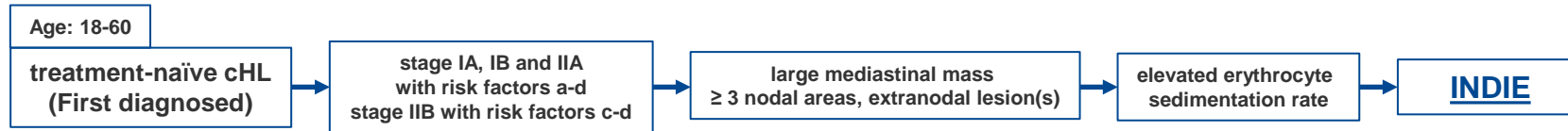
Currently no study options

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

# *Hodgkin's disease*

[continue...](#) →





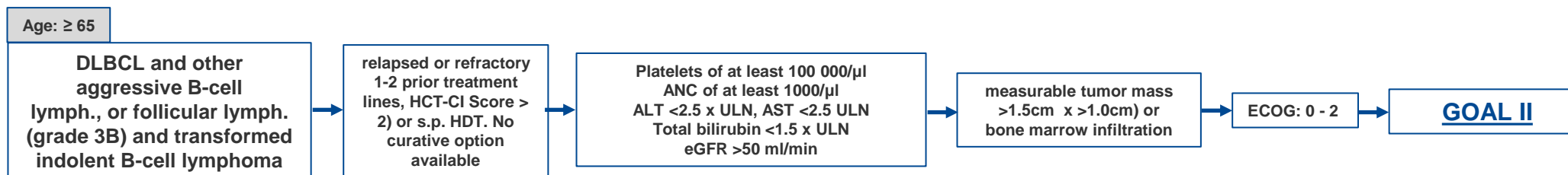
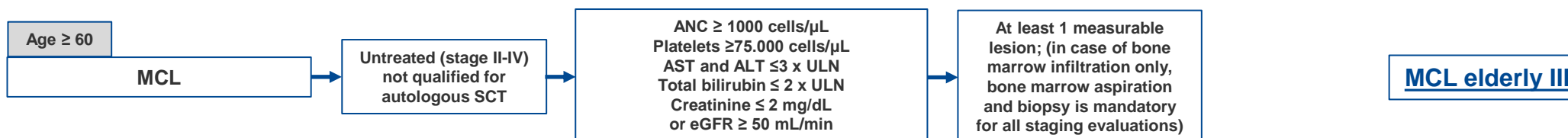
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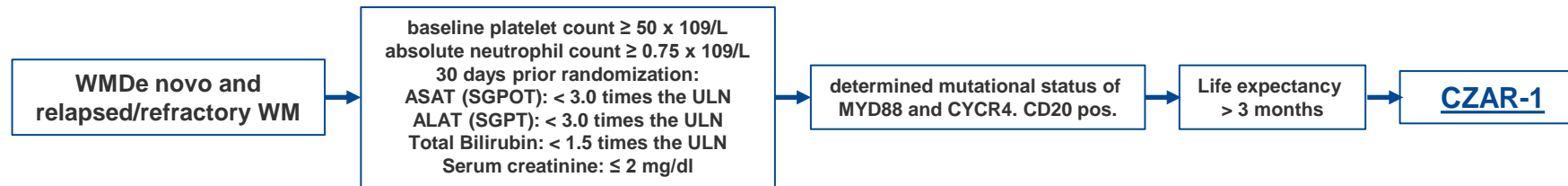
# Non-Hodgkin's lymphoma (NHL) & Waldenström's disease

29a

29b

[continue...](#) →





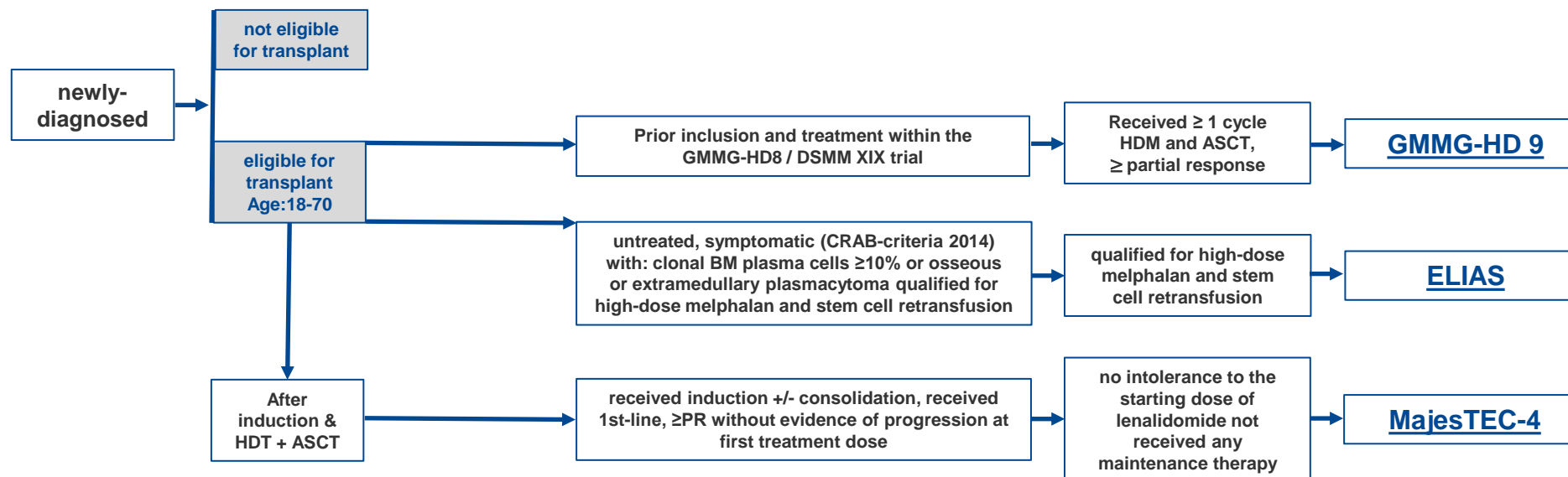
*Please also check the possibility of inclusion in the BASKET studies!*

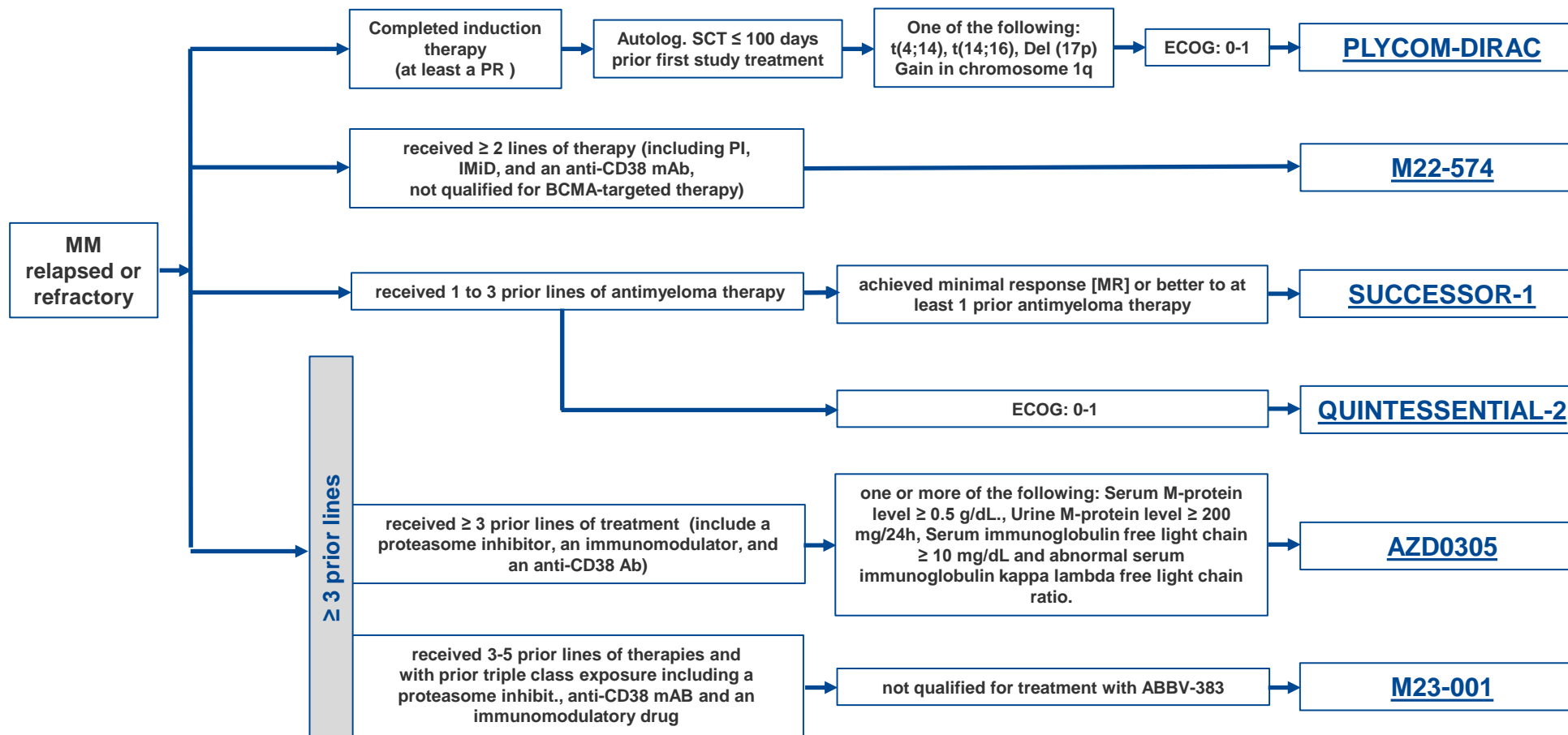
# *Multiple myeloma*

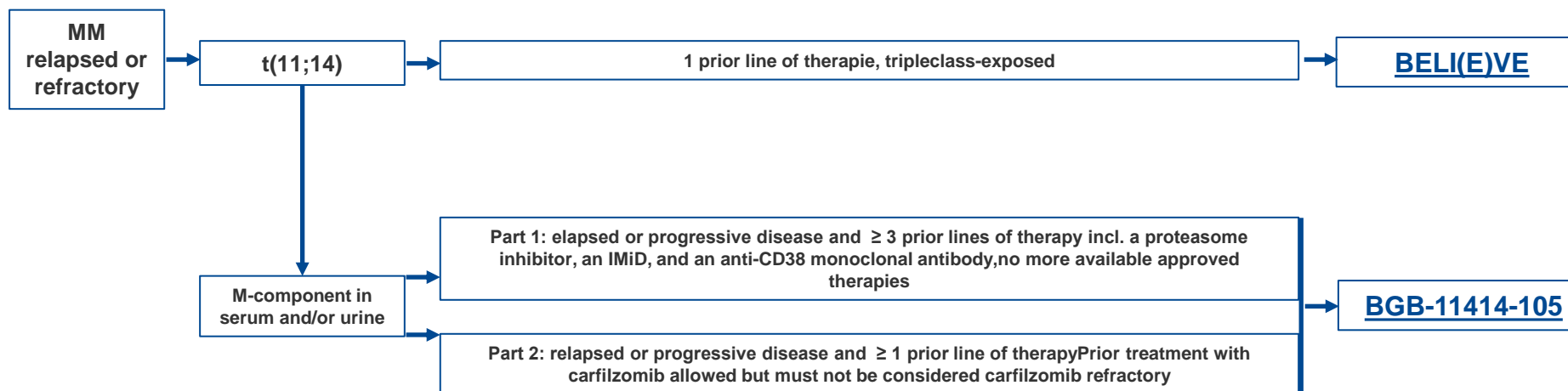
30a MM

30b r/r

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







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



# *Myelodysplastic syndrome (MDS)*

[continue...](#) →

Currently no study options

# *Anemia*

continue... →

Currently no study options

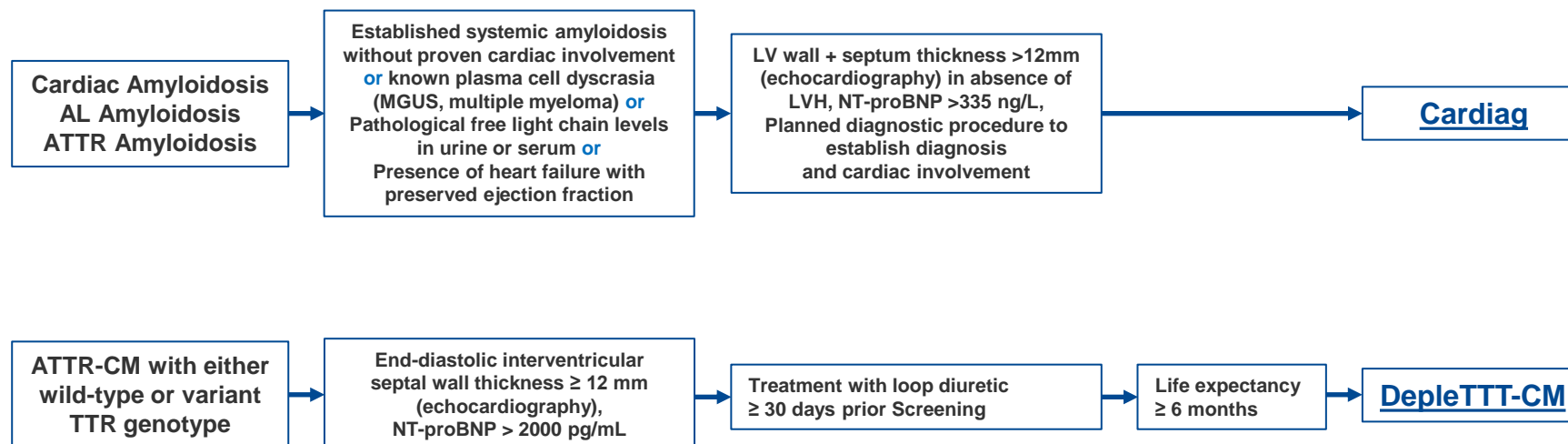
# *Immune thrombocytopenia (ITP)*

[continue...](#) →

Currently no study options

# *Amyloidosis*

[continue...](#) →

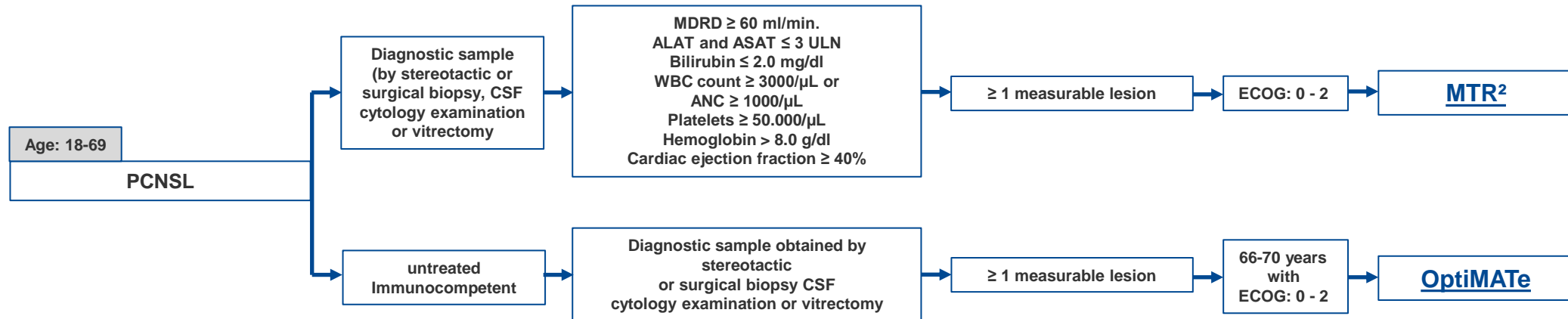


*Please also check the possibility of inclusion in the BASKET studies!*



# *Primary CNS lymphomas (PCNSL)*

[continue...](#) 



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

# *Palliative studies*

continue... →



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

# *Bronchial-Ca / Lung*

[continue...](#) →

## 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

**Recruitment Status:** **RECRUITING**

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

**Primary Completion Date:** 2029-10-31

**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  $\geq 50\%$

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](https://clinicaltrials.gov/NCT04613596)

Open, non-interventional, prospective, multi-center clinical research platform with the main objective to assess molecular biomarker testing, treatment and outcome of patients with NSCLC or SCLC in Germany

**Recruitment Status:** **RECRUITING**

**Condition:** Metastatic Non-small Cell Lung cancer (NSCLC)/ Non-small Cell Lung cancer Metastatic/ Non-small Cell Lung cancer Stage I,II or III/ Small-cell Lung cancer

**Primary Completion Date:** 2026-09

**Intervention/ Treatment:** Other: **data collection**

**Inclusion Criteria:**

Patients who meet all of the following criteria are eligible for the project:/ Age ≥ 18 years/ Able to understand and willing to sign written Informed Consent and to complete patient-reported-outcome assessment instruments/ Main project (Metastatic NSCLC):/ Confirmed non-small cell lung cancer (NSCLC)/ Informed consent no later than four weeks after start of first-line systemic treatment or no later than four weeks after diagnosis for patients receiving "best supportive care only"/ Stage IV, or stage IIIB/C (UICC8) if patient is ineligible for curative surgery and/or radiochemotherapy / Systemic therapy or best supportive care/ Satellite Stage I/II/III (NSCLC):/ Confirmed non-small cell lung cancer (NSCLC)/ Informed consent no later than four weeks after start of first anti-tumor treatment (including surgery and radiotherapy) or no later than four weeks after diagnosis for patients receiving "best supportive care only" (i.e. no anti-tumor treatment = no surgery, radiotherapy or systemic therapy)/ Stage I, Stage II, stage IIIA, or stage IIIB/C (UICC8)/ Systemic (chemo)therapy and/or radiation therapy and/or surgery or best supportive care/ Satellite SCLC/ Confirmed Small cell lung cancer (SCLC) Informed consent no later than four weeks after start of first anti-tumor treatment or no later than four weeks after diagnosis for patients receiving "best supportive care only" (i.e. no anti-tumor treatment = no surgery, radiotherapy or systemic therapy)/ Systemic (chemo)therapy and/or radiation therapy and/or surgery or best supportive care

see [Link](#):

[clinicaltrials.gov/NCT02622581](https://clinicaltrials.gov/NCT02622581)

CONTACT:		Lungenklinik Großhansdorf	
Prof. Dr. med. Martin Reck Dr. med. Marlitt Horn	04102 / 601 2101	<a href="mailto:m.reck@lungenclinik.de">m.reck@lungenclinik.de</a>	
	04102 / 601 2104	<a href="mailto:m.horn@lungenclinik.de">m.horn@lungenclinik.de</a>	
CONTACT:		HOPA	
PD. Dr. med. Gunter Schuch Stefanie Behrendt-Hanausch	040 38 02 12 4250	<a href="mailto:info@hopa.de">info@hopa.de</a>	
		<a href="mailto:info@hopa.de">info@hopa.de</a>	
CONTACT:		MVZ für Onkol. und Urolo. GmbH, Wilhelmshaven	
Dr. med. Gerald Rodemer Wittmer Eva (SC)	04421 95600-40	<a href="mailto:wittmer@onko-uro.de">wittmer@onko-uro.de</a>	

Phase 2, Randomized, Open-label Platform Study Utilizing a Master Protocol to Evaluate Novel Immunotherapy Combinations in Participants with Previously Untreated Locally Advanced/Metastatic Programmed Death Ligand 1-Positive Non Small Cell Lung cancer

Recruitment Status: **ACTIVE,NOT RECRUITING**

Condition: Non-small Cell Lung cancer

Primary Completion Date: ongoing

Intervention/ Treatment: DRUG: Pembrolizumab/ Dostarlimab/ Dostarlimab + Belrestotug/ Dostarlimab + GSK6097608 + Belrestotug

**Inclusion Criteria:**

Is capable of giving signed informed consent / Is, at the time of signing the ICF, at least 18 years old or the legal age of consent in the jurisdiction in which the study is taking place. / Has a histologically or cytologically confirmed diagnosis of locally advanced unresectable NSCLC not eligible for curative surgery and/or definitive radiotherapy with or without chemotherapy or metastatic NSCLC (squamous or nonsquamous). Mixed tumors will be categorized by the predominant cell type; if small cell or neuroendocrine elements are present, the participant is ineligible. / Has not received prior systemic therapy for their locally advanced or metastatic NSCLC. / **NOTE:** Completion of treatment with cytotoxic chemotherapy and/or radiation as part of neoadjuvant/adjuvant therapy is allowed if therapy was completed at least 6 months prior to the diagnosis of locally advanced or metastatic disease. Prior treatment with neoadjuvant/adjuvant immunotherapy is not permitted. / Has a PD-L1-high tumor performed locally or confirmed via central testing. / Has measurable disease based on RECIST 1.1 (Appendix 7), as determined by the investigator. / Has an ECOG PS 0 or 1. / Has adequate organ function / 9. If of childbearing potential, female participants must be willing to use adequate contraception.

see [Link](#):

[clinicaltrials.gov/NCT05565378](https://clinicaltrials.gov/NCT05565378)

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## A Phase 2, Open-Label, Parallel Cohort Study of Subcutaneous Amivantamab in Multiple Regimens in Patients With Advanced or Metastatic Solid Tumors Including EGFR-mutated Non-Small Cell Lung cancer

**Recruitment Status:** **RECRUITING**

**Condition:** Carcinoma, Non-small-Cell Lung

**Primary Completion Date:** 2025-10-31

**Intervention/ Treatment:** DRUG: **Amivantamab/ Lazertinib/ Carboplatin/ Pemetrexed/ Direct Oral Anticoagulant (DOAC)/ Low Molecular Weight Heparin (LMWH)**

### Inclusion Criteria:

Participant must have histologically or cytologically confirmed, locally advanced or metastatic, non-small cell lung cancer (NSCLC) that is not amenable to curative therapy including surgical resection or chemoradiation. Additional Cohort specific disease requirements include: Cohorts 1, 3, 3b, 5, 6 and 7: epidermal growth factor receptor (EGFR) exon 19 deletion (Exon19del) or Exon 21 L858R mutation; Cohort 2: EGFR Exon 20ins mutation. Cohorts 1,5,and6: Participant should not have received any prior systemic therapy for locally advanced or metastatic NSCLC. Cohort 2: Participant should not have received any prior systemic therapy for locally advanced or metastatic NSCLC. Cohorts 3and3b: Participant must have progressed on or after osimertinib monotherapy as the most recent line of treatment. Osimertinib must have been administered as either the first-line treatment for locally advanced or metastatic disease or in the second-line setting after prior treatment with first- or second-generation EGFR tyrosine kinase inhibitor (TKI) as a monotherapy. Cohort 4: Participants need to currently be on an amivantamab IV Q2W regimen (1,050 mg or 1,400 mg depending on weight) for at least 8 weeks, as part of SoC, an expanded access program, or as a rollover from a long-term extension, without any amivantamab dose reduction. Cohort 7: Participants must have progressed on or after the combination of amivantamab and lazertinib as the most recent line of treatment. The combination of amivantamab and lazertinib must have been administered as the first-line treatment for locally advanced or metastatic disease. Cohort 2, 3, 3b, and 7 only: Squamous NSCLC are excluded. EGFR mutation must have been identified as determined by Food and Drug Administration (FDA) approved or other validated test of either circulating tumor deoxyribonucleic acid (ctDNA) or tumor tissue in a clinical laboratory improvement amendments (CLIA) certified laboratory (sites in the United states [US]) or an accredited local laboratory (sites outside of the US). A copy of the initial test report documenting the EGFR mutation must be included in the participant records and a deidentified copy must also be submitted to the sponsor/ All cohorts except Cohort 4: Participants must have at least 1 measurable lesion, according to Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1. If the only target lesion has been previously irradiated, it must show signs of disease progression since radiation was completed If only 1 non-irradiated measurable lesion exists, which undergoes a biopsy and is acceptable as a target lesion, the baseline tumor assessment scans should be performed at least 14 days after the biopsy/ May 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(s)/ Have adequate organ (renal, hepatic, hematological, coagulation and cardiac) functions/ Participant must have eastern cooperative oncology group (ECOG) status of 0 or 1/ Cohort 6: Must be eligible for, and agree to comply with, the use of prophylactic anticoagulation with a direct oral anticoagulant or a low molecular weight heparin during the first 4 months of study treatment( A participant must agree not to donate eggs (ova, oocytes) or freeze for future use for the purposes of assisted reproduction during the study and for a period of 6 months after receiving the last dose of study treatment. Female participants should consider preservation of eggs prior to study treatment as anti-cancer treatments may impair fertility

**see Link:**

[clinicaltrials.gov/NCT05376891](https://clinicaltrials.gov/NCT05376891)

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## A Randomized Prospective Trial of Adjuvant Chemotherapy in Patients with Completely Resected Stage I or IIA Non-Squamous Non-Small Cell Lung cancer Identified as High or Intermediate Risk by a 14-Gene Prognostic Assay

**Recruitment Status:** **RECRUITING**

**Condition:** Completely resected stage I or IIA non-squamous non-small cell lung cancer (NSCLC)

**Primary Completion Date:** /

**Intervention/ Treatment:** DRUG: **Placebo/ Cisplatin, Vinorelbine Tartrate/ Pemetrexed/ Carboplatin INN/ Paclitaxel**

### Inclusion Criteria:

Written informed consent (the informed consent document must have been approved by the appropriate Institutional Review Board/Independent Ethics Committee (IRB/IEC). Consent must be obtained and signed and witnessed PRIOR to any study specific activity. / Age  $\geq 18$  years / Able to comply with the protocol, including acceptable candidacy for adjuvant chemotherapy consisting of cisplatin or carboplatin along with paclitaxel, vinorelbine or pemetrexed, according to investigator choice and administered in accordance with the protocol SmPCs and likely compliance with follow-up for anticipated length of study (i.e. 5 years from the initiation of enrollment). / Willing to be randomized to chemotherapy. / Histologically documented completely resected (R0) Stage I or IIA non-squamous NSCLC per 8th edition, TNM staging system. Mixed histologies that include a squamous cell or small cell or neuroendocrine component are eligible for the study, as long as they contain at least some component that is neither squamous cell, nor small cell nor neuroendocrine. Eligible resections include segmentectomy, lobectomy, bi-lobectomy, sleeve lobectomy, and pneumonectomy. Resections via wedge resection will not be eligible. Complete resection must also be accompanied by mediastinal lymph node sampling via mediastinoscopy, bronchoscopic sampling (e.g., endobronchial ultrasound guided biopsy) or surgical sampling. Nodes must be sampled from at least one of the following nodal stations: levels 2, 4, 7, 8, 9 for a right-sided cancer and levels 2, 4, 5, 6, 7, 8, 9 for left-sided cancers. / Adequate tissue sample available for 14-Gene Prognostic Assay (paraffin block with tumor occupying at least 25% of the tissue surface area) / Life expectancy excluding NSCLC diagnosis  $\geq 5$  years / ECOG performance status 0-1 / - Completely healed incisions / **For Germany:** Women without childbearing potential or women of childbearing potential who have a negative hCG pregnancy test (either serum or urine) and who agree to meet one of the following criteria from the first administration of chemotherapy, during the treatment and for a period of 6 months following the last administration of chemotherapy: / • Correct use of two reliable contraception methods. This includes every combination of a hormonal implant, transdermal hormonal patch, hormonal vaginal device, hormonal injection or of an intrauterine device or system (IUD/IUS) with a barrier method (condom or occlusive cap), / True abstinence (periodic abstinence and withdrawal are not acceptable methods of contraception), / Sexual relationship only with female partners and/or sterile male partners. / Men who agree to meet one of the following criteria from the first administration of chemotherapy, during the treatment and for a period of 6 months following the last administration of chemotherapy: / Correct use of two reliable contraception methods with female partners. This includes every combination of a hormonal implant, transdermal hormonal patch, hormonal vaginal device, hormonal injection or of an intrauterine device or system (IUD/IUS) with a barrier method (condom or occlusive cap), / True abstinence (periodic abstinence and withdrawal are not acceptable methods of contraception), / • Sexual relationship only with male partners and/or sterile female partners.

see [Link](#):

**2013-001494-24**

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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)

**Recruitment Status:** **RECRUITING**

**Condition:** Metastatic Non-small Cell Lung cancer

**Primary Completion Date:** 2028-02-29

**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.

**see Link:**

[clinicaltrials.gov/NCT05215340](https://clinicaltrials.gov/NCT05215340)

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This is an open-label randomized, controlled, multicenter, phase II trial with two arms. Patients with metastatic TTF-1 negative, treatment-naïve 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.

**Recruitment Status:** **RECRUITING**

**Condition:** Metastatic Non-small Cell Lung cancer Metastatic

**Primary Completion Date:** 2025-10

**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 10<sup>9</sup>/L/ Platelets ≥ 100 x 10<sup>9</sup>/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](https://clinicaltrials.gov/NCT05689671)

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## An Open-label, Multi-center Phase II Dose Selection Trial of Intravenous BI 764532, a DLL3-targeting T Cell Engager, in Patients With Relapsed/Refractory Extensive-stage Small Cell Lung cancer and in Patients With Other Relapsed/Refractory Neuroendocrine Carcinomas

**Recruitment Status:** **ACTIVE, NOT RECRUITING**

**Condition:** Small Cell Lung Carcinoma, Neuroendocrine Neoplasms

**Primary Completion Date:** 2025-09-25

**Intervention/ Treatment:** DRUG: BI 764532, formulation 1 + 2

### Inclusion Criteria:

Male or female participants ≥18 years old and at least at the legal age of consent in countries where it is greater than 18 years at the time of signature of the informed consent form (ICF). Signed and dated written informed consent in accordance with International Council for Harmonisation-Good Clinical Practice (ICH-GCP) and local legislation prior to admission to the trial. Histologically or cytologically confirmed, cancer of the following histologies: /Small cell lung cancer (SCLC)/ Extra-pulmonary neuroendocrine carcinoma (epNEC) (except Merkel cell carcinoma (MCC), Medullary thyroid cancer (MTC) and Neuroendocrine prostate cancer (NEPC))/ Large cell neuroendocrine carcinoma (LCNEC) of the lung Patients with tumors with mixed histologies for any above type are eligible only if the neuroendocrine carcinoma/small tumour cells component is predominant and represents at least 50% of the overall tumour tissue. Patients must have progressed or recurred after SoC therapy/ SCLC: after at least two prior lines of therapy, including at least one platinum-based regimen; in countries where SoC in first line therapy includes PD-L1 inhibitor treatment patients should have received the combination of platinum-based regimen plus PD-L1 inhibitor unless they have been unable to receive checkpoint inhibitor treatment. / epNEC/LCNEC: after at least one platinum-based regimen/ Eastern Cooperative Oncology Group (ECOG) score of 0 or 1./ Measurable lesions as defined per Response Evaluation Criteria In Solid tumors (RECIST) v 1.1 within 21 days prior to the first dose of BI 764532./ Availability of archival tumour tissue sample./ Adequate organ function as defined in the protocol. All toxicities related to previous anti-cancer therapies have resolved = Common Terminology Criteria for Adverse Events (CTCAE) Grade 1 prior to trial treatment administration (except for alopecia, peripheral neuropathy, fatigue and endocrinopathies controlled by replacement therapy which must be = CTCAE Grade 2 and amenorrhea/menstrual disorders which can be any grade). Women of childbearing potential (WOCBP) and men able to father a child must be ready and able to use highly effective methods of birth control per ICH M3 (R2) that result in a low failure rate of less than 1% per year when used consistently and correctly. A list of contraception methods meeting these criteria and instructions on the duration of their use is provided in the participant information

see [Link:](#)

[clinicaltrials.gov/NCT05882058](https://clinicaltrials.gov/NCT05882058)

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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

Recruitment Status: **RECRUITING**

Condition: Non Small Cell Lung cancer  
Primary Completion Date: 2028-03-21  
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.

see [Link](#):

[clinicaltrials.gov/NCT04928846](https://clinicaltrials.gov/NCT04928846)

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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

Recruitment Status: **RECRUITING**

Condition: Non-Small Cell Lung cancer

Primary Completion Date: 2027-04

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:

see *Link*:

[clinicaltrials.gov/NCT05142189](https://clinicaltrials.gov/NCT05142189)

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

**Recruitment Status:** **RECRUITING**

**Condition:** NSCLC Stage IIIB or IV

**Primary Completion Date:** 2026-07-06

**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  $\geq$  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 or 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

see [Link](#):

[clinicaltrialsregister.eu 2019-004757-88](https://clinicaltrialsregister.eu/2019-004757-88)

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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).

**Recruitment Status:** **RECRUITING**

**Condition:** Metastatic Non-Small Cell Lung cancer

**Primary Completion Date:** 2028-05-30

**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  $\geq 2$  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](https://clinicaltrials.gov/NCT05984277)

## 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

**Recruitment Status:** **RECRUITING**

**Condition:** Carcinoma, Non-Small Cell Lung

**Primary Completion Date:** 2027-12-01

**Intervention/ Treatment:** DRUG: Entrectinib, 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  $\leq 50\%$  observed during screening for the study

History of prolonged corrected QTc interval / Peripheral sensory neuropathy  $\geq$  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](https://clinicaltrials.gov/NCT04603807)

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# A Phase 1/2 Study of the Selective Anaplastic Lymphoma Kinase (ALK) Inhibitor NVL-655 in Patients With Advanced NSCLC and Other Solid Tumors

Recruitment Status: **RECRUITING**

**Condition:** Locally advanced Solid Tumor, Metastatic Tumor

**Primary Completion Date:** 2026-02

**Intervention/ Treatment:** DRUG: **NVL-655**

**Inclusion Criteria:**

Age ≥18 years, Phase 2 Cohort 2f only: Age ≥12 years and weighing >40 kg.

**Phase 1:** Histologically or cytologically confirmed locally advanced or metastatic solid tumor with a documented ALK rearrangement or activating ALK mutation.

**Phase 2: Cohorts except 2f:** Histologically or cytologically confirmed locally advanced or metastatic NSCLC with a documented ALK rearrangement / **Cohort 2f:** Histologically or cytologically confirmed locally advanced or metastatic solid tumor with a documented ALK rearrangement or activating ALK mutation detected by certified assay.

**Phase 1:** Must have evaluable disease (target or nontarget) according to RECIST 1.1 Phase 2: Must have measurable disease according to RECIST 1.1 / Adequate organ function and bone marrow reserve

**Exclusion Criteria:**

Patient's cancer has a known oncogenic driver alteration other than ALK. / Known allergy/hypersensitivity to excipients of NVL-655. / Major surgery within 4 weeks of the study entry / Ongoing or anticancer therapy / Actively receiving systemic treatment or direct medical intervention on another therapeutic clinical study.

see [Link](#):

[clinicaltrials.gov/NCT05384626](https://clinicaltrials.gov/NCT05384626)

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A Multicentre, Phase II, Single-Arm, Interventional Study of Neoadjuvant Durvalumab and Platinum-based Chemotherapy (CT), Followed by Either Surgery and Adjuvant Durvalumab or Chemoradiotherapy (CRT) and Consolidation Durvalumab, in Participants With Resectable or Borderline Resectable Stage IIB-IIIB Non-small Cell Lung Cancer

**Recruitment Status:** RECRUITING

**Condition:** non-small Cell Lung Cancer

**Primary Completion Date:** 2026-04-01

**Intervention/ Treatment:** DRUG: Durvalumab

**Inclusion Criteria:**

Deemed resectable or borderline resectable at baseline, confirmed by MDT evaluation at diagnosis. / Previously untreated and pathologically confirmed Stage IIB to select [i.e.N2] Stage IIIB by AJCC v8. / Nodal status confirmed with whole body FDG-PET and biopsy via endobronchial ultrasound, mediastinoscopy, or thoracoscopy. / Mandatory brain MRI. / EGFR and ALK wild-type. / Medically operable: / adequate cardiac and lung function to undergo resection. / Participant must be ≥ 18 years, at the time of screening. / Histologically or cytologically documented NSCLC. / Minimum life expectancy of 12 weeks. / Minimum body weight of 30 kg. / Male and female participants must be willing to use acceptable methods of contraception. / Female participants of childbearing potential must have negative / pregnancy test.

**Exclusion Criteria:**

Unresectable NSCLC confirmed by MDT evaluation at baseline / Stage IIIC patients / Participants whose planned surgery at enrollment is a wedge resection / Known EGFR mutation or ALK translocation / Participants contraindicated for surgical intervention due to comorbid conditions / Participants who are allergic to study intervention. / Participants with more than one primary tumour. / Known active hepatitis infection, positive HCV antibody, HBsAg or HBV core antibody (anti-HBc), at screening. / Female participants who are pregnant or breastfeeding. / Judgement by the investigator that the participant should not participate in the study. / Previously infected or tested positive for human immunodeficiency virus.

see [Link](#):

[clinicaltrials.gov/NCT05925530](https://clinicaltrials.gov/NCT05925530)

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# A Randomized, Phase 3, Open-label Study to Evaluate Sigvotatug Vedotin Compared With Docetaxel in Adult Participants With Previously Treated Non-small Cell Lung Cancer

Recruitment Status: **RECRUITING**

Condition: Carcinoma, Non-small-Cell Lung  
 Primary Completion Date: 2028-01-31  
 Intervention/ Treatment: DRUG: Sigvotatug Vedotin/ Docetaxel

**Inclusion Criteria: /**  
 Histologically or cytologically confirmed diagnosis of locally advanced, unresectable (Stage IIIB, IIIC), or metastatic Stage IV (M1a, M1b, or M1c) NSCLC American Joint Committee on Cancer (AJCC) Staging Manual, Version 8.0, and the Union for International Cancer Control (UICC) Staging System (Eighth edition). / Participants must have NSCLC with nonsquamous histology / Tumors with squamous, or predominantly squamous histology are excluded. / Tumors with small cell elements are excluded. / Participants who have NSCLC with known actionable genomic alteration (AGAs) are permitted / Participants must have received the following prior therapies and progressed during or relapsed after receiving their most recent prior therapy: / **Participants with no known AGAs must fulfill 1 of the following conditions:** Received a platinum-based combination therapy for the treatment of metastatic or recurrent disease and a PD-(L)1 monoclonal antibody (concurrently or sequentially with platinum-based chemotherapy), unless contraindicated. / Experienced disease progression within 6 months of the last dose of platinum-based chemotherapy in the adjuvant or neoadjuvant setting and received a PD-(L)1 monoclonal antibody at any time during the course of treatment. / Participants with known AGAs must fulfill the following conditions: / Must have received at least 1 relevant AGA targeted therapy and in the opinion of the investigator, additional AGA targeted therapy is not in the best interest of the participant. / Received a platinum-based combination therapy for the treatment of metastatic or recurrent disease, or experienced disease progression within 6 months of the last dose of platinum-based chemotherapy in the adjuvant or neoadjuvant setting / May have received up to 1 PD-(L)1 monoclonal antibody (concurrently or sequentially with platinum-based chemotherapy). / Measurable disease based on RECIST v1.1 / Participants must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, with adequate baseline hematologic, hepatic, and renal function and measurable disease according to RECIST v1.1

**Exclusion Criteria:**  
 see [Link:](#)

[clinicaltrials.gov/NCT06012435](https://clinicaltrials.gov/NCT06012435)

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# *Head and neck tumors*

continue... →

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.

**Recruitment Status:** **RECRUITING**

**Condition:** Nasopharyngeal Carcinoma, Nasopharyngeal cancer, Nasopharyngeal Neoplasms, Nasopharynx cancer

**Primary Completion Date:** 2026-01-29

**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  $\geq 18$  years / Stage II or higher in patients  $\leq 25$  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  $\geq 18$  years) and patient prior to study participation

see [Link](#):

[clinicaltrials.gov/NCT06019130](https://clinicaltrials.gov/NCT06019130)

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## 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

**Recruitment Status:** **RECRUITING**

**Condition:** Unresectable Head and Neck Squamous Cell Carcinoma, Metastatic Head and Neck cancer, Recurrent Head and Neck cancer

**Primary Completion Date:** 2028-05

**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<sup>2</sup> 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](https://clinicaltrials.gov/NCT04534205)

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## A Phase III Trial of Risk-stratified, Reduced Intensity Adjuvant Treatment in Patients Undergoing Transoral Surgery for Human Papillomavirus (HPV)-Positive Oropharyngeal cancer

**Recruitment Status:** **RECRUITING**

**Condition:** Human Papillomavirus (HPV)-Positive Oropharyngeal cancer

**Primary Completion Date:** 2026-10

**Intervention/ Treatment:** DRUG: **Cisplatin**\_RADIATION: Postoperative Radiotherapy

**Inclusion Criteria:** Histologically confirmed or suspected squamous cell carcinoma of the oropharynx. /

UICC/AJCC TNM 7th edition stage T1-T3, N0-N2b (or UICC TNM 8th edition stage T1-T3, N0-N1) disease. /

Multidisciplinary team (MDT) decision to treat with primary transoral resection and neck dissection. / Patients considered fit for surgery and adjuvant radiotherapy / Aged 18 or over. /

Written informed consent provided.

**Exclusion Criteria:** Known HPV negative squamous cell carcinomas of the head and neck: A negative result for p16 Immunohistochemistry automatically excludes a patient from the trial. If initial p16 testing is positive but High Risk HPV (HR HPV) In-Situ Hybridization (ISH)/Polymerase Chain Reaction (PCR) does not demonstrate the presence of HR HPV DNA, the patient will also be excluded. Patients who are p16+ may complete swallowing assessments, excluding videofluoroscopy, and surgery whilst HR HPV DNA status is being determined (with recourse to central concordance testing, if appropriate, for UK centres). HPV positivity, as determined by p16 and the demonstration of HR HPV DNA is essential before patients undergo videofluoroscopy or randomisation. / T4 and/or T1-T3 tumors where transoral surgery is considered not feasible. / UICC/AJCC TNM 7th edition N2c-N3 nodal disease (or UICC/AJCC TNM 8th edition N2-N3 nodal disease). /

Patients for whom transoral surgery and neck dissection is not considered the primary treatment modality. /

Current smokers with clinically staged N2b disease (including smokers up to 6 months before diagnosis), even if HPV-positive. Vaping is permitted and should be considered as non-smoking status. /

Any pre-existing medical condition likely to impair swallowing function and/ or a history of pre-existing swallowing dysfunction prior to index oropharyngeal cancer. /

Patients with distant metastatic disease as determined by routine pre-operative staging radiological investigations e.g., CT thorax and upper abdomen or PET-CT. /

Patients with a history of malignancy in the last 5 years, except basal cell carcinoma of the skin or carcinoma in-situ of the cervix. /

Women who are pregnant or breastfeeding and fertile women who will not be using contraception during the trial.

**see Link:**

[clinicaltrials.gov/NCT02215265](https://clinicaltrials.gov/NCT02215265)

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## 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

**Recruitment Status:** **RECRUITING**

**Condition:** Neoplasms, Head and Neck

**Primary Completion Date:** 2028-05-04

**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](https://clinicaltrials.gov/NCT06256588)

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## A Phase 2, Randomized, Open-label, Platform Study Using a Master Protocol to Evaluate Novel Immunotherapy Combinations as First-Line Treatment in Participants With Recurrent/ Metastatic PD-L1 Positive Squamous Cell Carcinoma of the Head and Neck

**Recruitment Status:** **RECRUITING**

**Condition:** Neoplasms, Head and Neck

**Primary Completion Date:** 2027-05-14

**Intervention/ Treatment:** DRUG: **GSK6097608 (nelistotug)**, **GSK4057190 (dostarlimab)**, **GSK4428859A (belrestotug)**, **GSK4381562 (anti-PVRIG)**

**Inclusion Criteria:** Have histologically or cytologically-confirmed HNSCC that is R/M and is considered incurable by local therapies. A) Subjects must not have had prior systemic therapy administered in the R/M setting. Chemoradiation therapy which was completed more than 4 months prior to signing consent if given as part of multimodal treatment for locally advanced disease is allowed B) The eligible primary tumor locations are oropharynx, oral cavity, hypopharynx, and larynx C) Subjects may not have a primary tumor site of nasopharynx (any histology) / Has measurable (target) disease based on RECIST 1.1 as determined by the investigator. / Has an Eastern Cooperative Oncology Group performance status (ECOG PS) of 0 or 1 / Provides a tumor tissue sample obtained at the time of or after the initial diagnosis of R/M HNSCC. A fresh tumor tissue sample obtained within 90 days of screening is highly preferred, If fresh biopsy is not possible, an archival tumor specimen is acceptable unless it was obtained prior to administration of chemoradiation for the treatment of a participant's tumour. Needle or excisional biopsies or resected tissue is required. Cytological specimens such as fine needle aspirates, bone marrow samples, or cell blocks are not acceptable. Bone specimen is not acceptable. / Has tumor Programmed death ligand 1 (PD-L1) expression / If the primary tumor site is oropharyngeal carcinoma, the participant must have Human papillomavirus (HPV) results

**Exclusion Criteria:**

Has received prior therapy with any immune checkpoint inhibitors, including antibodies or drugs targeting Programmed death protein 1 (PD-1), PD-L1, Cytotoxic T-lymphocyte-associated protein 4 (CTLA-4), T cell immunoreceptor with immunoglobulin and immunoreceptor tyrosine based inhibitory motif domains (TIGIT), Cluster of differentiation (CD) 96, or other immune checkpoint pathways. / Participants with previous malignancies (except non-melanoma skin cancers, and the following in situ cancers: bladder, gastric, esophageal, colon, endometrial, cervical/dysplasia, melanoma, or breast) unless a complete remission was achieved at least 2 years prior to study entry AND no additional therapy is required during the study period. / Have active tumor bleeding or a high risk of bleeding (examples include but are not limited to radiographic evidence of major blood vessel invasion/infiltration or tumor demonstrates >90 degree abutment or encasement of a major vessel [carotid, jugular, bronchial artery] and/or exhibits other high-risk features such as arteriovenous fistula). / Has PD within 4 months of completion of curatively intended treatment for locoregionally advanced HNSCC / Participants with any carcinomatous meningitis or leptomeningeal spread and those with uncontrolled or symptomatic Central Nervous System (CNS) metastases / Active autoimmune disease that has required systemic disease-modifying or immunosuppressive treatment within the last 2 years. (Stable, medically managed autoimmune endocrinopathies are acceptable if participant otherwise meets entry criteria.)

see [Link](#):

[clinicaltrials.gov/NCT06256588](https://clinicaltrials.gov/NCT06256588)

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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

**Recruitment Status:** **RECRUITING**

**Condition:** Head and Neck Squamous Cell Carcinoma

**Primary Completion Date:** 2028-02

**Intervention/ Treatment:** DRUG: **Petosemtamab/ Investigators`choice**

**Inclusion Criteria:**

Signed ICF before initiation of any study procedures. / Age  $\geq 18$  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  $\geq 12$  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](https://clinicaltrials.gov/NCT06496178)

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.

**Recruitment Status:** **RECRUITING**

**Condition:** Head and Neck Squamous Cell Carcinoma

**Primary Completion Date:** 2028-01

**Intervention/ Treatment:** DRUG: **Petosemtamab/ Pembrolizumab**

**Inclusion Criteria:**

Signed ICF before initiation of any study procedures / Age  $\geq 18$  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  $\geq 1$ . / 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  $\geq 12$  weeks, as per investigator assessment. / Left ventricular ejection fraction (LVEF)  $\geq 50\%$  or  $\geq$  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  $\geq 300/\mu\text{l}$ , 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  $\leq$  Grade 1 or baseline except for Grade  $\leq 2$ - 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 treatment / The 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](https://clinicaltrials.gov/NCT06525220)

## 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

**Recruitment Status:** **RECRUITING**

**Condition:** Locally Advanced Head and Neck Squamous Cell Carcinoma

**Primary Completion Date:** 2029-01-19

**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](https://clinicaltrials.gov/NCT06129864)

# *Esophageal cancer*

[continue...](#) →

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

Recruitment Status: **RECRUITING**

**Condition:** Barrett Esophagus/ Barrett Adenocarcinoma/ Esophagus Neoplasm  
**Primary Completion Date:** 2025-10  
**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 esophageal 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](https://clinicaltrials.gov/NCT03427346)

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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

**Recruitment Status:** **RECRUITING**

**Condition:** Digestive System Diseases, esophageal SCC

**Primary Completion Date:** /

**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  $\geq 10$  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 esophageal 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](https://clinicaltrialsregister.eu/2018-002617-35)

## Surgery as needed versus surgery on principle in patients with postneoadjuvant clinical complete tumor response of esophageal cancer

**Recruitment Status:** **RECRUITING**

**Condition:** Malignant neoplasm of oesophagus

**Primary Completion Date:** 2027-10-31

**Intervention/ Treatment:** see Link!

### Inclusion Criteria:

Sex: All / EC (adenocarcinoma (EAC) and squamous cell carcinoma (ESCC)) according to the UICC definition (TNM8), / TNM stage: ycT0-3 ycN0 ycM0, / completion of neoadjuvant chemotherapy or neoadjuvant chemoradiation / no visible lymphatic or distant metastasis in routine postneoadjuvant CT, / ECOG Performance status 0-2 / Age ≥ 18 years

### Exclusion Criteria:

Key exclusion criteria: / Postneoadjuvant dysphagia / Tumors of the cervical esophagus / Tumors with direct proximity to the membranous part of the central airway / TNM stage cT4 or ycT4 / TNM stage cM1 or ycM1 / Postneoadjuvant esophageal obstruction / Local tumor progression during/after neoadjuvant therapy detected by endoscopy or cross-sectional imaging / Time since last day of neoadjuvant anti-cancer treatment ≥ 9 weeks / Co-morbidity with contraindication for major surgery / nCRT with >50 Gy radiation dose

**see Link:**

[Drks.de/DRKS00032613](https://drks.de/DRKS00032613)

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# *Gastric cancer and gastroesophageal junction*

continue... →

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

Recruitment Status: **RECRUITING**

Condition: Gastric cancer

Primary Completion Date: 2026-07-30

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 trastuzumab-containing 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](https://clinicaltrials.gov/NCT04379596)

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

**Recruitment Status:** **RECRUITING**

**Condition:** Gastric cancer, GastrEsophageal Junction Adenocarcinoma

**Primary Completion Date:** 2026-11-01

**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  $\geq 18$  and  $\leq 75$  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  $\leq 1$  / 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/NCT04379596](https://clinicaltrials.gov/NCT04379596)

## Randomized Trial Comparing Endoscopic Ultrasound-guided Gastrojejunostomy and Surgical Gastrojejunostomy in Gastric Outlet Obstruction

**Recruitment Status:** **RECRUITING**

**Condition:** Gastric Outlet Obstruction

**Estimated Completion Date:** 2025-12

**Intervention/ Treatment:** PROCEDURE: EUS-guided gastrojejunostomy/ Procedure: Surgical gastrojejunostomy

**Inclusion Criteria:**

Age ≥ 18 years

Presence of gastric outlet obstruction on any imaging or endoscopy from known or suspected malignancy

Gastric outlet obstruction Scoring System (GOOSS) of ≤ 1 (defined as maximum oral intake of liquids only)

**Exclusion criteria:** Age < 18 years

Intrauterine pregnancy

Use of anticoagulants that cannot be discontinued for the procedure

Unable to obtain consent for the procedure from either the patient or LAR

**see Link:**

[clinicaltrials.gov/NCT06123468](https://clinicaltrials.gov/NCT06123468)

Minimally invasive versus open Gastrectomy. A multicenter randomized controlled trial.

Recruitment Status: **RECRUITING**

Condition: Malignant neoplasm of stomach

Estimated Completion Date: /

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](https://drks.de/DRKS00025765)

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## A Randomized, Open-label Phase II/III Efficacy and Safety Study of Atezolizumab in Combination With FLOT Versus FLOT Alone in Patients With Gastric Cancer and Adenocarcinoma of the Oesophago-gastric Junction and High Immune Responsiveness

Recruitment Status: **RECRUITING**

**Condition:** Gastric Cancer, Gastroesophageal Junction Adenocarcinoma

**Estimated Completion Date:** 2027-05-31

**Intervention/ Treatment:** PROCEDURE: DRUG: **Atezolizumab/ 5-Fluorouracil/ Calciumfolinat/ Oxaliplatin/ Docetaxel**

### Inclusion Criteria:

Have provided written informed consent / In the investigator's judgement, is willing and able to comply with the study protocol including the planned surgical treatment / Female and male patients\*  $\geq 18$  years of age / Diagnosed with histologically confirmed adenocarcinoma of the GEJ (Type I-III) or the stomach (cT2, cT3, cT4, any N category, M0), or (any T, N+, M0) that: / s not infiltrating any adjacent organs or structures by CT or MRI evaluation / does not involve peritoneal carcinomatosis / is considered medically and technically resectable Note: the absence of distant metastases must be confirmed by CT or MRI of the thorax and abdomen, and, if there is clinical suspicion of osseous lesions, a bone scan. If peritoneal carcinomatosis is suspected clinically, its absence must be confirmed by laparoscopy. Diagnostic laparoscopy is mandatory in patients with T3 or T4 tumors of the diffuse type histology in the stomach or upon request of the central review. / No prior cytotoxic or targeted therapy / No prior partial or complete esophagogastric tumor resection / ECOG  $\leq 1$  / Phase II only: Availability of a representative tumor specimen that is suitable for determination of PD-L1 and MSI status; MSI assessment will be performed locally or centrally, and result must be available prior to randomization (for details, see chapter 9). PD-L1 will be assessed centrally but is not used for enrolment of the patients. The analysis requires paraffin embedded biopsy samples of the tumor. / Phase III only: Assessment of MSI and PD-L1 [and optional TMB/EBV] must be performed locally and results for either of the following MSI-high, PD-L1 CPS $\geq 1$ , TMB  $\geq 10$ /MB or EBV+ must be available prior to randomization (for details, see chapter 9). / Females 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 5 months after the last study treatment. A woman is considered to be of childbearing potential if she is postmenarcheal, has not reached a postmenopausal state (has not had  $\geq 12$  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 implants, established, proper use of combined oral or injected hormonal contraceptives, and certain 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. / Males must agree to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agree to refrain from donating sperm, as defined below: / a. 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 3 months after the last dose of study treatment to avoid exposing the embryo. Men must refrain from donating sperm during this same period. Men with a pregnant partner must agree to remain abstinent or to use a condom for the duration of the pregnancy. / Criterion integrated in criterion 9. / Adequate hematological, hepatic and renal function as indicated by the following parameters: / Leukocytes  $\geq 3.000/\text{mm}^3$ , platelets  $\geq 100.000/\text{mm}^3$  without transfusion, absolute neutrophil count (ANC)  $\geq 1500/\text{mm}^3$  without granulocyte colony-stimulating factor support, Hemoglobin  $\geq 90$  g/L (9 g/dL) - Patients may be transfused to meet this criterion. / Bilirubin  $\leq 1.5$  x upper limit of normal, aspartate transaminase and alanine transaminase  $\leq 2.5$  x upper limit of normal, alkaline phosphatase  $\leq 2.5$  x upper limit of normal / Serum creatinine  $\leq 1.5$  x upper limit of normal, or glomerular filtration rate  $> 45$  ml/min (calculated using the Cockcroft-Gault formula) / Serum albumin  $\geq 25$  g/L (2.5 g/dL) / For patients not receiving therapeutic anticoagulation: INR or aPTT  $\leq 1.5$  x ULN; for patients receiving therapeutic anticoagulation: stable anticoagulant regimen \*There are no data that indicate special gender distribution. Therefore, patients will be enrolled in the study gender-independently.

see Link:

[clinicaltrials.gov/NCT03421288](https://clinicaltrials.gov/NCT03421288)

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# *Pancreatic cancer*

[continue...](#) →

## Effect of an additional brown foot point anastomosis in patients after pancreatic head resection

Recruitment Status: **RECRUITING**

**Condition:** pancreatic head resection

**Estimated Completion Date:** /

**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

**Recruitment Status:** **RECRUITING**

**Condition:** Extrahepatic bile duct

**Primary Completion Date:** 31.12.2028

**Intervention/ Treatment:** PROCEDURE: **Roboterassistierte Pankreatoduodenektomie/ Offene Pankreatoduodenektomie**

**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/m<sup>2</sup> / Participation in another study with an effect on the outcome

**see Link:**

[Dpcg.nl](https://dpcg.nl)

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## Intensified treatment in patients with oligometastatic pancreatic cancer - multimodal surgical treatment versus systemic chemotherapy alone: a randomized controlled trial

Recruitment Status: **RECRUITING**

Condition: oligometastatic pancreatic cancer

Estimated Completion Date: /

Intervention/ Treatment: Analytical,Diagnostic,Therapeutic Techniques and Equipment [E]-Surgical Procedures, Operative

### Inclusion Criteria:

Age  $\geq 18$  years and  $\leq 80$  years / histologically or cytologically confirmed metastatic adenocarcinoma of the pancreas / medical and technical operability of the primary tumor / limited synchronous liver metastatic status ( $\leq 3$  resectable/ablative treatable liver metastases) **OR** limited metachronous liver metastatic status ( $\leq 3$  resectable/ ablative treatable liver metastases), but must have completed adjuvant chemotherapy at least 6 months before start of study treatment / Previous neo-/adjuvant anti-cancer therapy for non-metastatic PDAC with last dose administered  $\geq 6$  months before the start of study treatment are allowed, adequate hematological (WBC  $\geq 3000/\mu\text{l}$ , platelets  $\geq 100.000/\mu\text{l}$ , hemoglobin  $\geq 8$  g/dl), hepatic (bilirubin  $\leq 2.5$  x mg/dl) and renal function (creatinine clearance  $>50$  ml/min) parameters / ECOG performance status  $\leq 1$  / Written informed consent obtained according to international guidelines and local laws / measurable disease according to RECIST v1.1. prior to induction therapy

### Exclusion Criteria:

Unresectable pancreatic cancer / Subject (male or female) is not willing to use highly effective methods of contraception (per institutional standard) during treatment and for 6 months (male or female) after the end of treatment (adequate: oral contraceptives, intrauterine device or barrier method in conjunction with spermicidal jelly) / Psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule. These conditions should be discussed with the patient before registration in the trial. / Prior chemotherapy within 6 months or prior radiation therapy within 28 days (e.g. in adjuvant settings). Exception for previous systemic anti-cancer treatment for metastatic PDAC: Patients with need of immediate treatment (high tumour load, symptoms) may have received one cycle of FOLFIRINOX or modified FOLFIRINOX prior to study entry (Cycle 0) and may be enrolled after Coordinating Investigator approval has been obtained. / Concurrent malignancy other than the disease under investigation with exception of malignancy that was treated curatively and has not recurred within 2 years prior to the date of screening. Fully resected basal or squamous cell skin cancers and any carcinoma in situ are eligible / Patients with either peritoneal carcinomatosis or  $>3$  liver metastases or extrahepatic metastasis) / Known hypersensitivity to the active substances or any of the excipients

[euclinicaltrials.eu:2023-503558-10-00](https://euclinicaltrials.eu/2023-503558-10-00)

see [Link](#):

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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

**Recruitment Status:** **RECRUITING**

**Condition:** Adenocarcinoma, Pancreatic Ductal

**Estimated Completion Date:** 2029-12-27

**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  $\geq 2$  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  $\geq 2$  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 glucuronosyltransferase 1A1 (UGT1A1).

**see Link:**

[clinicaltrials.gov/NCT05968326](https://clinicaltrials.gov/NCT05968326)

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# *Cholangiocellular carcinoma*

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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

**Recruitment Status:** **RECRUITING**

**Condition:** Extrahepatic bile duct

**Primary Completion Date:** 31.12.2028

**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](https://drks.de/DRKS00013276)

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## Phase 2 Study of Preoperative Gemcitabine Plus Cisplatin with Durvalumab (MEDI4736) and Tremelimumab in intrahepatic cholangiocarcinoma

**Recruitment Status:** **RECRUITING**

**Condition:** Intrahepatic cholangiocarcinoma

**Primary Completion Date:** /

**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. / 8. 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  $\geq 1.5 \times 10^9$  /L), **b.** Hemoglobin  $\geq 9$  g/dL (transfusion permitted within 30 days of study entry). **c.** Platelet count  $\geq 100 \times 10^9$ /L **d.** Serum bilirubin  $\leq 2.0 \times$  institutional upper limit of normal (ULN). **e.** Aspartate aminotransferase (AST) and alanine aminotransferase (ALT)  $\leq 3 \times$  ULN **f.** Creatinine normal for age: if serum creatinine is abnormal for age the patient must have a calculated creatinine clearance  $\geq 50$  mL/min using the CKD-EPI formula. **g.** Quick  $\geq 70\%$  or International normalized ratio (INR)  $\leq 1.2 \times$  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:**

[Clinicaltrialsregister.eu:2021-004411-11](https://clinicaltrialsregister.eu/2021-004411-11)

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Radiofrequency Ablation Via Catheter and Transpapillary Access in Patients With Cholangiocarcinoma

Recruitment Status: **RECRUITING**

**Condition:** Cholangiocarcinoma, Klatskin Tumor, Bile Duct Cancer, Liver Cancer

**Primary Completion Date:** 2026-01

**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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# *Small bowel cancer*

[continue...](#) →

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.

**Recruitment Status:** **RECRUITING**

**Condition:** Adenomatous Polyposis Coli, Familial Adenomatous Polyposis, Duodenal Adenoma

**Primary Completion Date:** 2025-01-30

**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](https://clinicaltrials.gov/NCT06435533)

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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

**Recruitment Status:** **RECRUITING**

**Condition:** Duodenum

**Primary Completion Date:** /

**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](https://drks.de/DRKS00029731)

# *Colorectal carcinoma/ colon*

[continue...](#) →

## Anatomical Resection of Liver MetAstases iN patlents With RAS-mutated Colorectal cancer

**Recruitment Status:** **RECRUITING**

**Condition:** Colorectal Liver Metastases

**Estimated Completion Date:** 2027-12

**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/NCT0678583](https://clinicaltrials.gov/NCT0678583)

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Epidemiological Study to Determine the Prevalence of ctDNA Positivity in Participants With Stage II (High Risk) or Stage III CRC After Surgery With Curative (R0) Intent and Subsequent Adjuvant Chemotherapy With Monitoring of ctDNA During Clinical Follow-up

Recruitment Status: **RECRUITING**

**Condition:** Colorectal cancer Stage II,Colorectal cancer Stage III

**Primary Completion Date:** 2025-03

**Intervention/ Treatment:** Procedure: Regular blood sample collection for ctDNA assessment

**Inclusion Criteria:**

Must have given informed consent indicating that they understand the purpose of and procedures required for the study and are willing to participate in the study. / Age ≥ 18 years old at time of signing the informed consent form. / Ability to comply with the study protocol, in the investigator's judgment. / Must have Stage II/Stage III rectal cancer or Stage II (high risk)/Stage III colon cancer per AJCC 2017 that has been surgically totally resected (R0 confirmed by pathology report). Stage II (high risk) colon cancer is defined as (any of): T4/ Grade ≥ 3/ Clinical presentation with bowel obstruction or perforation/ Histological signs of vascular, lymphatic or perineural invasion/ < 12 nodes examined / Adequate tumor material in formalin-fixed paraffin embedded (FFPE) blocks or as sectioned tissue (only upon approval by sponsor) must be available, preferably from resection. The specimen should be submitted along with an associated pathology report. Multiple samples may be provided as available, but priority should be given to tissue with the highest tumor content and lowest necrotic area. / Intention to receive a SoC adjuvant chemotherapy (AdCTx) within 8 weeks post-surgery, and be scheduled for at least 3 months of treatment (including rest days) according to the treating physician or investigator./ Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1./ Adequate end-organ function.

**Exclusion Criteria:**

Induction of neoadjuvant systemic therapy prior to resection of CRC. / Prior systemic investigational therapy. / Positive serology for hepatitis B (unless immune due to vaccination or resolved natural infection or unless passive immunization due to immunoglobulin therapy): Positive test for antibodies to hepatitis B core antigens (anti HBc) and Negative test for antibodies to hepatitis B surface antigens (anti HBs). / Active hepatitis C virus (HCV) infection; participants who have completed curative antiviral treatment with HCV viral load below the limit of quantification by polymerase chain reaction (PCR) are allowed. / Participant has a history of human immunodeficiency virus (HIV) antibody positivity, or tests positive for HIV at screening. / Residual tumor classification following surgery other than R0 (microscopic margin-negative resection). / Participants with known past or current malignancy other than inclusion diagnosis, except for: Cervical carcinoma of Stage 1B or less. / Non-invasive basal cell or squamous cell skin carcinoma. / Non-invasive, superficial bladder cancer./ Prostate cancer with a current PSA level < 0.1 ng/mL. Any curable cancer with a complete response (CR) of > 2 years duration. / Participant has not started SoC AdCTx within 8 weeks post-surgery. / Participant has received less than 3 months (including rest days) of AdCTx treatment. / Inadequate tumor material (either quality or quantity) to support circulating tumor DNA (ctDNA) analysis./ Participants who have had prior splenectomy.

see [Link](#):

[clinicaltrials.gov/NCT04813627](https://clinicaltrials.gov/NCT04813627)

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

**Recruitment Status:** **RECRUITING**

**Condition:** Colon cancer Stage II

**Primary Completion Date:** 2023-06

**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](https://clinicaltrials.gov/NCT04089631)

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AIO-KRK-0420 NeoBRAF is a single arm, multicenter, phase II trial with neoadjuvant encorafenib, binimetinib and cetuximab for patients with BRAF V600E mutated/pMMR localized colorectal cancer.

Recruitment Status: **RECRUITING**

**Condition:** Colorectal cancer, Colon Cancer, BRAF V600E, BRAF V600 Mutation, Localized cancer

**Estimated Completion Date:** 2025-01-31

**Intervention/ Treatment:** DRUG: **Binimetinib**

**Inclusion Criteria:**

Biopsy-confirmed adenocarcinoma of the colon or upper rectum if too high for radiotherapy. / Radiologically (CT/MRI) staged disease as: T3-4 (as invasion of surrounding tissue structures or organs) and/or nodal positive (N+ defined as regional lymph node(s) without fat hilus and short axis diameter of  $\geq 1$  cm), M0. BRAF V600E mutation and pMMR or MSS (as determined by a validated test, preferably PCR or NGS). ECOG performance status  $\leq 1$ . / Age  $\geq 18$  years. / Adequate hematologic function at screening as follows: ANC  $\geq 1.5 \times 10^9/L$ , platelets  $\geq 100 \times 10^9/L$ , hemoglobin  $\geq 9.0$  g/dL. / Adequate liver function at screening as measured by serum transaminases (AST & ALT)  $\leq 2.5 \times$  ULN and total bilirubin  $\leq 1.5 \times$  ULN. / Patients with known Gilbert disease who have serum bilirubin level  $\leq 3 \times$  ULN may be enrolled. / Adequate renal function at screening: serum creatinine  $\leq 1.5 \times$  ULN. / Adequate serum electrolytes at screening defined as serum potassium and magnesium levels within institutional normal limits (Note: replacement treatment to achieve adequate electrolytes will be allowed. / Adequate cardiac function at screening characterized by left ventricular ejection fraction (LVEF)  $\geq 50\%$  as determined by ECHO and QT interval corrected for heart rate using Fridericia's formula (QTcF) value  $\leq 480$  msec. / Negative serum pregnancy test at screening for women of childbearing potential. / Highly effective contraception for both male and female subjects if the risk of conception exists. (Note: The effects of the trial drugs on the developing human fetus are unknown; thus, women of childbearing potential and men able to father a child must agree to use highly effective contraception, defined as methods with a failure rate of less than 1 % per year, containing at least 1 form of non-hormonal contraception. / Highly effective contraception is required at least 28 days prior, throughout and for at least 6 months after interventional study treatment (encorafenib, binimetinib and cetuximab). / Signed and dated written informed consent. / Ability to take oral medication. / Ability to comply with the protocol for the duration of the study, including hospital/office visits for treatment and scheduled follow-up visits and examinations.

**Exclusion Criteria:** follow **Link**  
see **Link:**

[clinicaltrials.gov/NCT05510895](https://clinicaltrials.gov/NCT05510895)

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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).

**Recruitment Status:** RECRUITING

**Condition:** Colorectal cancer

**Primary Completion Date:** 2027-11

**Intervention/ Treatment:** DRUG: mFOLFOX/ mFOLFOXIRI/ FOLFIRI/ CAPOX

#### Inclusion Criteria:

Patient's signed informed consent. / Patient's age  $\geq 18$  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  $\geq 1.5 \times 10^9/L$  (1500/ $\mu L$ ) / Hemoglobin  $\geq 80$  g/L (8 g/dL) / Platelet count  $\geq 100 \times 10^9/L$  (100000/ $\mu L$ ) without transfusion / Total serum bilirubin of  $\leq 1.5 \times$  upper limit of normal (ULN) / Aspartate aminotransferase (AST/GOT)  $\leq 3.0 \times$  ULN. / Calculated glomerular filtration rate (GFR) according to Cockcroft-Gault formula or according to MDRD  $\geq 50$  mL/min or serum creatinine  $\leq 1.5 \times$  ULN / Patients without anticoagulation need to present with an INR  $< 1.5 \times$  ULN and PTT  $< 1.5 \times$  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 ( $\geq 12$  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](https://clinicaltrials.gov/NCT05008809)

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## A Phase I/II Trial of D,L-Methadone and mFOLFOX6 in Treatment of Advanced Colorectal cancer - The AIO-MEFOX Trial (AIO-KRK-0119)

**Recruitment Status:** **RECRUITING**

**Condition:** Chemo-refractory Colorectal Carcinoma

**Primary Completion Date:** 2025-06-15

**Intervention/ Treatment:** DRUG: **Maximum tolerated dose, MTD: D,L-methadone hydrochloride (Methasan® 10 mg/ml)**

### Inclusion Criteria:

Advanced, histologically confirmed, metastatic colorectal carcinoma not suitable for resection and chemorefractory or Previously employed chemotherapy regimens and agents should comprise the following: Fluoropyrimidines, oxaliplatin, irinotecan, antiangiogenic agents (bevacizumab, aflibercept or ramucirumab), anti-EGFR-mAbs (in case of all-Ras-wildtype and left-sided primary tumor) and Trifluridin/Tipiracil (TAS102) / Microsatellite stable subset (MSS) of colorectal cancer / Prior antineoplastic therapy or radiochemotherapy is allowed up to two weeks prior to start of the study medication. However, for the phase II part of the trial, failure of this strategy must be confirmed. In case of prior radiotherapy/radiochemotherapy the target lesion used for tumor evaluation must not be in the radiation field. / There must be an oxaliplatin free period of at least 6 months prior to start of the study medication. / No polyneuropathy of > grade 1 / Tumor-related ECOG performance status 0-2 / Anticipated life expectancy ≥ 12 weeks / Creatinine clearance ≥ 30 ml/min/ Serum total bilirubin level ≤ 3 x ULN/ ALT and AST ≤ 2.5 x ULN or ≤ 5.0 x ULN in the presence of liver metastasis (established after adequate biliary drainage) White blood cell count ≥ 3.5 x 10<sup>6</sup>/ml, neutrophil granulocytes count ≥ 1,5 x 10<sup>6</sup>/ml, platelet count ≥ 100 x 10<sup>6</sup>/ml/ Pain that has to be controllable without concomitant use of opioids / Signed informed consent according to ICH/GCP and national/local regulations (participation in translational research is obligate) / None of the following concomitant medications: MAO-B-Inhibitors, strong inducers or inhibitors of CYP3A4, antiarrhythmic drugs of class I and III or other drugs that have potential for QT-prolongation/ Age ≥ 18 years / At least one measurable target lesion according to RECIST 1.1. Pre-irradiated or locally treated lesions must not be used as target lesions.

**Exclusion Criteria:** Microsatellite unstable CRC (MSIhigh) / Chronic infectious diseases, immune deficiency syndromes / Polyneuropathy >grade I according to CTCAE V4.03 / Premalignant hematologic disorders, e.g. myelodysplastic syndrome / Disability to understand and sign written informed consent document / Past or current history of malignancies except for the indication under this study and curatively treated: / Basal and squamous cell carcinoma of the skin/ In-situ carcinoma of the cervix / Other malignant disease without recurrence after at least 3 years of follow-up / Clinically significant cardiovascular disease (incl. myocardial infarction, unstable angina, symptomatic congestive heart failure, serious uncontrolled cardiac arrhythmia) 6 months before enrollment / History of or evidence upon physical examination of CNS disease unless adequately treated (e.g. primary brain tumor, seizure not controlled with standard medical therapy or history of stroke). / Severe non-healing wounds, ulcers or bone fractures / Evidence of bleeding diathesis or coagulopathy / Patients not receiving therapeutic anticoagulation must have an INR ≤ 1.4 or PTT ≤ 40 sec within 28 days prior to randomization. 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) / Major surgical procedures or significant traumatic injury within 28 days prior to randomization, or anticipation of the need for major surgical procedure during the course of the study. / Pregnancy or breastfeeding women. / Use of cannabinoids because of overlapping and/or potentiating of potential side effects / Concomitant daily use of opioids in the last 3 months including methadone prior start of study medication / Subjects with known allergies to the study drugs or to any of its excipients. / Treatment with another investigational drug or participation in another interventional trial (within the 14 days prior randomization or 5 plasma half-lives of the used investigational drug, whatever is longer) / congenital QT-syndrome. / Alcohol abuse. / Bronchial asthma. / Liver cirrhosis > Child-Pugh classification A. / Any psychological, familial, sociological or geographical condition potentially compromising compliance with the study protocol and the follow-up schedule; those conditions should be discussed with the patient prior to registration in the trial

see [Link](#):

[clinicaltrials.gov/NCT05212012](https://clinicaltrials.gov/NCT05212012)

#### CONTACT:

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

**Recruitment Status:** **RECRUITING**

**Condition:** Malignant neoplasm of the digestive organs in the family history

**Primary Completion Date:** /

**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](https://drks.de/DRKS00030695)

#### CONTACT:

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Tania Ruppenthal (SC)

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Incompletely ablated or recurrent adenomas in the colorectum should be resected. The resection methods EMR and FTRD will be compared in terms of safety and success.

Recruitment Status: **RECRUITING**

**Condition:** Recurrence or incompletely ablated non-lifting adenoma in the colorectum

**Primary Completion Date:** 2025-06

**Intervention/ Treatment:** ?

**Inclusion Criteria:**

Recurrence or incompletely ablated adenoma in the colorectum - minimum size 5 mm, maximum size 3 cm

**Exclusion Criteria:**

Biopsy evidence of a carcinoma or high probability of the presence of a carcinoma - Localisation in the lowest rectum (0-3 cm from ano) - Stenosis in the colorectum - Age <18 years - Lack of consent (possibility)

**see Link:**

Further Information: not available

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## A Randomized, Open Label, Multicenter Phase II/III Trial of Sacituzumab Govitecan Compared to Standard of Care in Metastatic, Refractory Colorectal Cancer Patients

**Recruitment Status:** **RECRUITING**

**Condition:** Metastatic Colorectal Cancer

**Primary Completion Date:** 2028-08-01

**Intervention/ Treatment:** DRUG: Sacituzumab Govitecan/ Physicians Choice

### Inclusion Criteria:

Patients meeting all of the following criteria are considered for admission to the trial: / Diagnosis of UICC Stage IV mCRC, not eligible for local therapy / Women or men aged  $\geq 18$  years, no upper age limit / ECOG performance status  $\leq 2$  / Patients must have failed standard therapy or were intolerable towards standard therapy which must include fluoropyrimidine, oxaliplatin and irinotecan. (Targeted therapies (in combination with chemotherapy) including antiangiogenic monoclonal antibody/fusion protein/small molecule (e.g. bevacizumab, aflibercept, ramucirumab) and anti-EGFR antibody (e.g. Cetuximab, Panitumumab) are allowed as previous therapies.) / No Irinotecan treatment within the last 6 months. Patients that received Irinotecan treatment more than 6 months prior to inclusion, must have been responsive to Irinotecan induction therapy (i.e., patients previously exposed to induction chemotherapy containing irinotecan must have presented CR or PR or else SD at least 3 months or at initial response assessment). / At least one measurable lesion according to RECIST 1.1 that can be accurately assessed at screening by computed tomography or magnetic resonance imaging and is suitable for repeated assessment or available CT scan of thorax and abdomen not older than 30 days before start of treatment (day 1 of cycle 1). / Written informed consent / Non-pregnant and non-nursing women of childbearing potential (WOCBP) must have a negative serum or urine pregnancy test within a sensitivity of at least 25 mIU/mL within 72 hours prior to start of study treatment. A woman is considered of childbearing potential, i.e. fertile, following menarche and until becoming post-menopausal unless permanently sterile. / Permanent sterilization methods include hysterectomy, bilateral salpingectomy and bilateral oophorectomy. / Post-menopausal or evidence of non-childbearing status is defined within this clinical trial: / Amenorrhea for at least 12 consecutive months without an alternative medical cause following cessation of exogenous hormonal treatments. / Chemotherapy-induced menopause with  $>1$  year interval since last menses / Surgical sterilisation / WOCBP are to be advised using two effective methods of birth control to avoid pregnancy throughout the study and for at least 6 months after the last dose of IMP. This includes effective contraception methods that can achieve a failure rate of less than 1% per year (e.g. hormonal contraceptive and condom, IUD/IUS and condom) or sterilization, resulting in a failure rate less than 1% per year. / Fertile men should not donate sperm and must be willing and able to use two effective methods of birth control (e.g latex condoms plus hormonal contraception in their partner) throughout the study and for at least 6 months after the last dose of IMP, if their sexual partners are WOCBP (acceptable methods see above). A man is considered fertile after puberty unless permanently sterile by bilateral orchidectomy.

see Link:

[clinicaltrials.gov/NCT056243393](https://clinicaltrials.gov/NCT056243393)

# 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

Recruitment Status: **RECRUITING**

Condition: Metastatic Colorectal Neoplasms

Primary Completion Date: 2025-08-31

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](https://clinicaltrials.gov/NCT05253651)



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

**Recruitment Status:** **RECRUITING**

**Condition:** Functional bowel disorder, unspecified

**Primary Completion Date:** /

**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 mmHg, diastolic > 100 mmHg; > 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](https://drks.de/DRKS00025802)

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X

Recruitment Status: **RECRUITING**

Condition:  
Primary Completion Date:  
Intervention/ Treatment:  
**Inclusion Criteria:**  
**Exclusion Criteria:**  
.  
*see Link:*



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# *Urothelial bladder cancer*

[continue...](#) →

## A Phase II Open-Label Study of Sacituzumab Govitecan in Unresectable Locally Advanced/Metastatic Urothelial cancer.

**Recruitment Status:** **RECRUITING**

**Condition:** Metastatic Urothelial cancer

**Primary Completion Date:** 2030-06

**Intervention/ Treatment:** DRUG: **Sacituzumab Govitecan-hziy/ Pembrolizumab/ Cisplatin/ Avelumab/ Zimberelimab/ Carboplatin/ Gemcitabine/ Domvanalimab**

### Inclusion Criteria:

Female or male individuals,  $\geq 18$  years of age (19 Years old for South Korea). / Individuals with histologically confirmed urothelial cancer (UC). / Eastern Cooperative Oncology Group (ECOG) Performance status score of 0 or 1. / **Cohort 1:** Have had progression or recurrence of urothelial cancer following receipt of platinum-containing regimen (cisplatin or carboplatin): / Received a first-line platinum-containing regimen in the metastatic setting or for inoperable locally advanced disease; Or received neo/adjuvant platinum-containing therapy for localized muscle-invasive urothelial cancer, with recurrence/progression  $\leq 12$  months following completion of therapy. / **Cohort 1:** In addition to above criterion, have had progression or recurrence of urothelial cancer following receipt of an Anti-programmed Cell Death Protein 1 (anti-PD-1)/ Anti-programmed Death Ligand 1 (PD-L1) therapy. / **Cohort 2:** Were ineligible for platinum-based therapy for first line metastatic disease and have had progression or recurrence of urothelial cancer after a first-line therapy for metastatic disease with anti-PD-1/PD-L1 therapy. Individual may not have received any platinum for treatment of recurrent, metastatic or advanced disease. / **Cohort 3:** Progression or recurrence of UC following a platinum containing regimen in the metastatic setting, or progression or recurrence of UC within 12 months of completion of platinum-based therapy as neoadjuvant or adjuvant therapy. / **Cohort 4:** Individual has not received any platinum-based chemotherapy in the metastatic or unresectable locally advanced setting. Creatinine clearance of at least 50 mL/min calculated by Cockcroft-Gault formula or another validated tool. For individuals receiving cisplatin at 70 mg/m<sup>2</sup> on Day 1 of every 21-day cycle, a creatinine clearance of at least 60 mL/min calculated by Cockcroft-Gault formula or another validated tool is required. Individuals with creatinine clearance between 50 to 59 mL/min are to receive a split dose of cisplatin (35 mg/m<sup>2</sup> Day 1 and Day 8 of every 21-day cycle). / **Cohorts 4, 5, 6:** Archival tumor tissue comprising muscle-invasive or metastatic urothelial carcinoma, or a biopsy of metastatic urothelial carcinoma. / **Cohort 5:** Individuals received at least 4 cycles and no more than 6 cycles of GEM + cisplatin. No other chemotherapy regimens are allowed in this cohort, with the exception of prior adjuvant or neoadjuvant systemic therapy with curative intent after > 12 months from completion of therapy. / No evidence of progressive disease following completion of first-line chemotherapy (ie, CR, PR, or SD per RECIST v1.1 guidelines as per investigator). / Treatment-free interval of 4 to 10 weeks since the last dose of chemotherapy. / **Cohort 6:** Cis-ineligible and no prior therapy for metastatic disease or for unresectable locally advanced disease. Checkpoint inhibitor therapy naïve or >12 months from completion of adjuvant therapy are permitted / **Cohorts 4 and 6:** Have measurable disease by CT or MRI as per RECIST 1.1 criteria. Tumor lesions situated in a previously irradiated area are considered measurable if progression has been demonstrated in such lesions. / **Cohorts 1, 2, 3 and 5:** Creatinine clearance  $\geq 30$  mL/min as calculated by the Cockcroft-Gault formula unless otherwise specified/ Adequate renal and hepatic function. / Adequate hematologic parameters without transfusional support./ Individuals must have a 3-month life expectancy.

see [Link](#):

[clinicaltrials.gov/NCT03547973](https://clinicaltrials.gov/NCT03547973)

## 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

**Recruitment Status:** **RECRUITING**

**Condition:** Muscle Invasive Urothelial cancer

**Primary Completion Date:** 2028-11-06

**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](https://clinicaltrials.gov/NCT06534983)

#### CONTACT:

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# *Prostate cancer*

[continue...](#) →

## A Randomized, 2-cohort, Double-blind, Placebo-controlled, Phase III Study of Saruparib (AZD5305) in Combination With Physician's Choice New Hormonal Agents in Patients With HRRm and Non-HRRm Metastatic Castration-Sensitive Prostate cancer (EvoPAR-Prostate01)

**Recruitment Status:** **RECRUITING**

**Condition:** Metastatic Castration-Sensitive Prostate cancer

**Primary Completion Date:** 2028-02-11

**Intervention/ Treatment:** DRUG: **Saruparib/ Placebo/ Abiraterone Acetate/ Darolutamide/ Enzalutamide**

### Inclusion Criteria:

Male  $\geq 18$  years of age. / Histologically documented prostate adenocarcinoma which is de novo or recurrent and castration-sensitive. Participants with pathologic features of small cell, neuroendocrine, sarcomatoid, spindle cell, or signet cell histology are not eligible. / Metastatic disease as documented by the investigator prior to randomisation, with clear evidence of  $\geq 1$  bone lesion and/or  $\geq 1$  soft tissue lesion that is suitable for repeated assessment with CT and/or MRI. / Participant is receiving ADT with a GnRH analogue or has undergone bilateral orchiectomy starting  $\geq 14$  days and  $< 4$  months prior to randomisation. / ECOG performance status of 0 or 1 with no deterioration over the 2 weeks prior to randomisation. / Provision of FFPE tumour tissue sample and blood sample (for ctDNA). / Confirmed HRRm status by central tumour tissue and/or ctDNA test is required to determine cohort eligibility. / Adequate organ and bone marrow function as described in study protocol. / Participants must not father children or donate sperm from signing ICF, during the study intervention and for 6 months after the last dose of study intervention. / Participants must use a condom from signing ICF, during study intervention, and for 6 months after the last dose of study drug, with all sexual partners.

### Exclusion Criteria:

Participants with a history of MDS/AML or with features suggestive of MDS/AML (as determined by prior diagnostic investigation). In case there is no clinical MDS/AML suspicion, no specific screening for MDS/AML (by BM/bone biopsy) is required. / Participants with any known predisposition to bleeding. / Any history of persisting ( $> 2$  weeks) severe cytopenia. / Refractory nausea and vomiting, chronic gastrointestinal diseases, inability to swallow the formulated product or previous significant bowel resection that would preclude adequate absorption of AZD5305 and/or the assigned NHA. / History of another primary malignancy, with exceptions. / Persistent toxicities (CTCAE Grade  $\geq 2$ ) caused by previous anticancer therapy. / Spinal cord compression or brain metastases unless symptomatic, stable, and not requiring steroids for at least 4 weeks prior to start of study intervention. / Cardiac criteria, including history of arrhythmia and cardiovascular disease. / Any prior anticancer pharmacotherapy or surgery for metastatic prostate cancer, with exceptions. / Prior treatment within 14 days with blood product support or growth factor support. / Participants who are unevaluable for both bone and soft tissue progression.

see [Link](#):

[clinicaltrials.gov/NCT06120491](https://clinicaltrials.gov/NCT06120491)

# 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

**Recruitment Status:** **RECRUITING**

**Condition:** Biochemically Recurrent Prostate cancer

**Primary Completion Date:** 2027-01-29

**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<sup>9</sup>/L (participant must not have received any growth factor within 4 weeks prior to sample being taken); Platelet count ≥100x10<sup>9</sup>/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<sup>2</sup> 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](https://clinicaltrials.gov/NCT05794906)

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# 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

**Recruitment Status:** RECRUITING

**Condition:** Prostate cancer  
**Primary Completion Date:** 2025-04  
**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](https://clinicaltrials.gov/NCT06122584)

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

**Recruitment Status:** **RECRUITING**

**Condition:** Metastatic Castration-Resistant Prostate cancer

**Primary Completion Date:** 2027-10-22

**Intervention/ Treatment:** DRUG: **Olaparib 400 mg/ Docetaxel 75 mg/m<sup>2</sup>/ 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](https://clinicaltrials.gov/NCT02861573)

## 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

**Recruitment Status:** **RECRUITING**

**Condition:** Prostatic cancer Metastatic

**Primary Completion Date:** 2028-08-02

**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 / Participants 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](https://clinicaltrials.gov/NCT06136624)

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## Prospective randomized trial to evaluate the prognostic role of lymphnode dissection in men with prostate cancer treated with radical prostatectomy

Recruitment Status: **RECRUITING**

**Condition:** Prostate cancer

**Estimated Completion Date:** 2027-12

**Intervention/ Treatment:** PROCEDURE: lymph node dissection

**Inclusion Criteria:**

localized intermediate risk prostate cancer (intermediate risk (PSA> 10 ng / ml - 20 ng / ml or Gleason score 7 or cT category 2b) / scheduled for open radical prostatectomie or DaVinci prostatectomie

**Exclusion Criteria:**

American Society of Anesthesiology Classification> 3 / Existing contraindications for performing a lymph node dissection / Neoadjuvant hormone therapy

*see Link:*

[clinicaltrials.gov/NCT04269512](https://clinicaltrials.gov/NCT04269512)

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

Recruitment Status: **RECRUITING**

Condition: Prostate cancer  
 Estimated Completion Date: 2025-12-31  
 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 to 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](https://clinicaltrials.gov/NCT04271579)

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# Active Surveillance Plus (AS+): Local Tumor Control With High-intensity Focused Ultrasound (HIFU) in Patients With Localized Prostate cancer

Recruitment Status: **RECRUITING**

Condition: Prostate cancer  
 Estimated Completion Date: 2030-09  
 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](https://clinicaltrials.gov/NCT04271579)

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## 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

**Recruitment Status:** **RECRUITING**

**Condition:** Prostate cancer

**Estimated Completion Date:** 2026-06-21

**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](https://clinicaltrials.gov/NCT06613100)

## 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)

**Recruitment Status:** **RECRUITING**

**Condition:** Prostatic Neoplasms, Castration-Resistant

**Estimated Completion Date:** 2028-03-31

**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](https://clinicaltrials.gov/NCT06353386)

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

**Recruitment Status:** **RECRUITING**

**Condition:** Metastatic Castration-Resistant Prostate Cancer

**Completion Date:** 2028-11-30

**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. / previous 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](https://clinicaltrials.gov/NCT06629779)

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

**Recruitment Status:** **RECRUITING**

**Condition:** Metastatic Castration-Resistant Prostate Cancer (mCRPC)

**Completion Date:** 2028-10-29

**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 Cooperative 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](https://clinicaltrials.gov/NCT06551324)

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# *Neuroendocrine tumors / carcinomas*

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Currently no study options

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# *Breast cancer*

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A Randomized, Open-label, Phase 3 Study of Sacituzumab Govitecan Versus Treatment of Physician's Choice in Patients With Previously Untreated, Locally Advanced, Inoperable or Metastatic Triple-Negative Breast cancer Whose Tumors Do Not Express PD-L1 or in Patients Previously Treated With Anti-PD-(L)1 Agents in the Early Setting Whose Tumors Do Express PD-L1

**Recruitment Status:** **RECRUITING**

**Condition:** Triple Negative Breast cancer, PDL-1 Positive

**Primary Completion Date:** 2028-07

**Intervention/ Treatment:** DRUG: **Sacituzumab Govitecan-hziy, Paclitaxel, nab-Paclitaxel, Gemcitabine, Carboplatin**

**Inclusion Criteria:**

Individuals, regardless of race and ethnic group, with previously untreated locally advanced, inoperable or metastatic triple-negative breast cancer (TNBC) / Individuals whose tumors are programmed cell death ligand 1 (PD-L1) negative at screening or individuals whose tumors are PD-L1 positive at screening if they have received an anti-PD-(L)1 inhibitor in the (neo) adjuvant setting or if they cannot be treated with a checkpoint inhibitor due to a comorbidity / Centrally confirmed TNBC and PD-L1 status on fresh or archival tissue / Individuals must have completed treatment for Stage I-III breast cancer, if indicated, and ≥ 6 months must have elapsed (with the exception of endocrine therapy) between completion of treatment with curative intent and first documented local or distant disease recurrence / Individuals presenting with de novo metastatic TNBC are eligible / Measurable disease based on computed tomography (CT) or magnetic resonance imaging (MRI) in accordance with per Response / Evaluation Criteria in Solid Tumors (RECIST) Version 1.1. as evaluated locally/ Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 / Demonstrates adequate organ function / Male individuals and female individuals of childbearing potential who engage in heterosexual intercourse must agree to use protocol-specified method(s) of contraception / Individuals with human immunodeficiency virus (HIV) must be on antiretroviral therapy (ART) and have a well-controlled HIV infection/disease

**Exclusion Criteria:**

Positive serum pregnancy test or women who are lactating / Received systemic anticancer treatment within the previous 6 months or radiation therapy within 2 weeks prior to enrollment / Have not recovered from adverse events (AEs) due to a previously administered agent at the time study entry / May not be participating in a study with an investigational agent or investigational device within 4 weeks prior to randomization. Individuals participating in observational studies are eligible / Previously received topoisomerase 1 inhibitors or antibody drug conjugates containing a topoisomerase inhibitor/ Active second malignancy / Active serious infection requiring antibiotics / Positive for HIV-1 or 2 with a history of Kaposi sarcoma and/or Multicentric Castleman Disease / Active hepatitis B virus (HBV) or hepatitis C virus (HCV) infection / Note: Other protocol defined Inclusion/Exclusion criteria may apply.

see [Link](#):

[clinicaltrials.gov/NCT05382299](https://clinicaltrials.gov/NCT05382299)

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## Adj. Dynamic Marker - Adjusted Personalized Therapy Comparing Abemaciclib Combined With Standard Adjuvant Endocrine Therapy Versus Standard Adjuvant Endocrine Therapy in (Clinical or Genomic) High Risk, HR+/HER2- EBC

**Recruitment Status:** **RECRUITING**

**Condition:** Breast cancer Female

**Primary Completion Date:** 2026-08

**Intervention/ Treatment:** DRUG: **Abemaciclib 50 MG; 150mg 1-0-1 per os**

### **Inclusion Criteria:** Prior to **REGISTRATION**

Written informed consent prior to any study procedures (outcomes of standard-of-care procedures performed before signing of informed consent by the patient but within allowed screening period can be used for screening of patient). / Female. /  $\geq 18$  years of age. **EITHER:** (Post)menopausal status at the time of initiation of adjuvant study medication, patient underwent bilateral oophorectomy, **or** age  $\geq 60$ , **or** age  $< 60$  and amenorrhea for 12 or more months (in the absence of chemotherapy, tamoxifen, or ovarian suppression) **and/or** FSH and estradiol in the postmenopausal range per local normal range. / **OR:** Pre-/perimenopausal patients: confirmed negative serum or urine pregnancy test ( $\beta$ -hCG) before starting study treatment, **or** patient has had a hysterectomy. / Histologically confirmed diagnosis (by local laboratory) of estrogen-receptor positive and/or progesterone-receptor positive ( $>1\%$ ) primary early breast cancer or local relapse. In case the receptor status from local pathology is unclear a central pathology review is obligatory. Results must be known prior to randomization. / Patient has HER2-negative breast cancer defined as a negative in-situ hybridization test or an IHC status of 0, 1+, or 2+, if IHC is 2+, a negative in-situ hybridization (FISH, CISH, or SISH) test is required (based on the analyzed tissue sample at initial diagnosis by a local laboratory). / 7. Patients are eligible with completed (i.e., 5 years according to SoC), planned or ongoing adjuvant endocrine therapy, without any signs of distant relapse or secondary malignancy **AND** if primary diagnosis was 6 years or less before enrollment / Intermediate to high clinical or genomic risk, defined as either one of the following criteria: c or p or ypN 2-3 with/without (neo)adjuvant chemotherapy; in patients with c/ypN0-1: non-pCR in patients with G3 or c/ypN1 high biological risk defined as G3 with Ki-67  $\geq 40\%$  **or** high genomic risk (RS  $> 25$  (known or Oncotype Dx® in screening phase) or another test) / high CTS5 score or UICC stage IIb (clinical if neoadjuvant chemotherapy or pathological) / **if patients do not fulfill above criteria:** patients  $\leq 50$  years old or pre-/perimenopausal and c or (y)pN1 disease (in particular if ET-non-response or no chemotherapy) / patients  $> 50$  years old and postmenopausal and c or (y)pN1 with intermediate genomic risk (RS  $\geq 18$ ) or non-low risk by another test / ET non-response definition: Ki-67 post-treatment  $> 10\%$  (central or local pathology value) / Patients after isolated locoregional relapse with high-risk patterns (e.g., rpT2-3 or rpN1-3 or G3 or Ki-67 pre-treatment  $\geq 20\%$ ), once surgery with free margins was completed **Note:** Inclusion is only possible for the first locoregional relapse removed by surgery (free margins) / Patients with any high clinical risk at Investigator's assessment but not fulfilling above criteria: consultation with sponsor required **Prior to RANDOMIZATION** Completed primary therapy of breast cancer according to current guidelines, i.e., after (neo)adjuvant treatment, definite surgery and radiotherapy, if applicable. / No clinical evidence of distant metastasis (confirmation recommended prior to randomization by either combination of or either one of the following examinations: CT thorax / abdomen, chest X-ray, liver ultrasound, bone scan, PET-CT). / Patient has available tumor tissue from primary diagnostic biopsy. / No contraindication for adjuvant ET. / Eastern Cooperative Oncology Group (ECOG) performance status 0-1. / Patient has adequate bone marrow and organ function as defined by the following laboratory values: absolute neutrophil count  $\geq 1.5 \times 10^9/L$ , platelets  $\geq 100 \times 10^9/L$ , hemoglobin  $\geq 8.0$  g/dL, total bilirubin  $\leq 1.5$  ULN, except for patients with Gilbert's Syndrome who may only be included if the total bilirubin is  $\leq 2.0 \times$  ULN or direct bilirubin within normal ranges, aspartate transaminase (AST)  $\leq 3 \times$  ULN, alanine transaminase (ALT)  $\leq 3 \times$  ULN, serum creatinine  $\leq 1.5 \times$  ULN. / Ability to swallow abemaciclib tablets or to administer other study medication, respectively. / Ability to communicate with the investigator and comply with study procedures. / Willing to receive therapy by clinical site, as required by the protocol.

see [Link](#):

[clinicaltrials.gov/NCT04565054](https://clinicaltrials.gov/NCT04565054)

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MZ-HH		Agaplesion Diakonieklinikum Hamburg	
Prof. Dr. med. Felix Hilpert Studienzentrale Silke Kassner	040-44190- 69/670 studien@mammazentrum.eu	Studienzentrale Mirjam Ahrens	040 790 20 2595 <a href="mailto:mirjam.ahrens@agaplesion.de">mirjam.ahrens@agaplesion.de</a>

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

**Recruitment Status:** **RECRUITING**

**Condition:** Breast cancer Female

**Primary Completion Date:** 2026-10

**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  $\geq 18$  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/NCT04565054](https://clinicaltrials.gov/NCT04565054)

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This is a Phase III, randomized, open-label, 3-arm, multicenter, international study assessing the efficacy and safety of Dato-DXd with or without durvalumab compared with ICT in participants with stage I to III TNBC with residual invasive disease in the breast and/or axillary lymph nodes at surgical resection following neoadjuvant systemic therapy

**Recruitment Status:** **RECRUITING**

**Condition:** Breast cancer

**Primary Completion Date:** 2027-09-20

**Intervention/ Treatment:** Drug: **Dato-DXd/ Durvalumab/ Capecitabine/ Pembrolizumab**

#### Inclusion Criteria:

Participant must be ≥ 18 years at the time of screening. / Histologically confirmed invasive TNBC, as defined by the ASCO/CAP guidelines. / Residual invasive disease in the breast and/or axillary lymph node(s) at surgical resection following neoadjuvant therapy. / Completed at least 6 cycles of neoadjuvant therapy containing an anthracycline and/or a taxane with or without platinum chemotherapy, with or without pembrolizumab. / No evidence of locoregional or distant relapse. / Surgical removal of all clinically evident disease in the breast and lymph nodes. / ECOG performance status of 0 or 1 with no deterioration over the previous 2 weeks prior to randomisation. / All participants must provide an FFPE tumour sample from residual invasive disease at surgery for tissue-based analysis. / No adjuvant systemic therapy. / Radiotherapy (if indicated) delivered before the start of study intervention. / If post-operative radiation therapy is given, an interval of no more than 6 weeks between the completion of radiation therapy and the date of randomisation (radiation therapy can be completed during screening period). If no post-operative radiation therapy is given, an interval of no more than 16 weeks between the date of breast surgery and the date of randomisation. / Has LVEF ≥ 50% by either an ECHO or MUGA scan within 28 days before randomisation. / Eligible for one of the therapy options listed as investigator's choice per investigator assessment. / No known germline BRCA1 or BRCA2 pathogenic mutation. / Adequate bone marrow reserve and organ function within 7 days before randomisation.

#### Exclusion Criteria:

Stage IV (metastatic) TNBC. / History of prior invasive breast cancer, or evidence of recurrent disease following preoperative therapy and surgery. / Severe or uncontrolled medical conditions including systemic diseases, history of allogeneic organ transplant and active bleeding diseases, ongoing or active infection, serious chronic gastrointestinal conditions associated with diarrhea chronic diverticulitis or previous complicated diverticulitis. / History of another primary malignancy except for adequately resected basal cell carcinoma of the skin or squamous cell carcinoma of the skin, in situ disease (including ductal carcinoma in situ) that has undergone potentially curative therapy, or other solid malignancy treated with curative intent with no known active disease within 5 years before randomisation and of low potential risk for recurrence. / Persistent toxicities caused by previous anticancer therapy, excluding alopecia, not yet improved to Grade ≤ 1 or baseline. Participants with irreversible toxicity that is not reasonably expected to be exacerbated by study intervention may be included (eg, hearing loss). / Active or prior documented autoimmune or inflammatory disorders. / Clinically significant corneal disease. / Active or uncontrolled hepatitis B or C virus infection. / Known HIV infection that is not well controlled. / Active tuberculosis infection. / Mean resting corrected QTcF > 470 ms regardless of gender, obtained from triplicate 12-lead ECGs performed at screening. / Uncontrolled or significant cardiac disease. / History of non-infectious ILD/pneumonitis including radiation, pneumonitis that required steroids, has current ILD/pneumonitis, or has suspected ILD/pneumonitis that cannot be ruled out by imaging at screening. / Has severe pulmonary function compromise. / Any known active liver disease. / Grade ≥ 2 peripheral neuropathy of any aetiology. / Prior exposure to a PD-1/PD-L1 inhibitor other than pembrolizumab. / Current or prior use of immunosuppressive medication within 14 days prior to randomisation. / Participants with a known severe hypersensitivity to Dato-DXd or any of the excipients of these products including but not limited to polysorbate 80 or other monoclonal antibodies. / Participants with a known severe hypersensitivity to PD-1/PD-L1 inhibitors. / Participation in another clinical study with a study intervention or investigational medicinal device administered in the last 4 weeks prior to randomisation, randomisation into a prior Dato-DXd, T-DXd, or durvalumab study regardless of treatment assignment. / Currently pregnant (confirmed with positive pregnancy test), breastfeeding or planning to become pregnant.

see [Link](#):

[clinicaltrials.gov/NCT05629585](https://clinicaltrials.gov/NCT05629585)

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

**Recruitment Status:** **RECRUITING**

**Condition:** HER2-Positive Early Breast cancer

**Primary Completion Date:** 2027-09-20

**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:

Non-operable breast cancer including inflammatory breast cancer / cT1a/b breast cancer / Any previous history of invasive breast cancer / Primary malignancies within 5 years, with the exception of adequately resected non-melanoma skin cancer, curatively treated in-situ disease / Any evidence for existing metastatic disease (confirmed by CT Thorax/Abdomen, bone scan, or other methods according to clinical practice / Previous or concurrent treatment with cytotoxic agents for any reason (except non-oncological reasons) / Concurrent treatment with other experimental drugs and participation in another clinical trial with any investigational drug within 30 days prior to study entry / Severe and relevant co-morbidity that would interact with the application of cytotoxic agents or the participation in the study/inadequate organ function / Reasons indicating risk of poor compliance / Woman of child-bearing potential defined as a woman physiologically capable of becoming pregnant, and not using highly effective methods of contraception during the study treatment and for 3 months after stopping the treatment. / Use of oral (oestrogen and progesterone), transdermal, injected, or implanted hormonal methods of contraception as well as hormonal replacement therapy. / Has substance abuse or any other medical conditions such as clinically significant cardiac or psychological conditions, that may, in the opinion of the investigator, interfere with the subject's participation in the clinical study or evaluation of the clinical study results. / Patients with a medical history of myocardial infarction (MI) within 6 months before randomisation, symptomatic congestive heart failure (CHF) (New York Heart Association Class II to IV), Subjects with troponin levels above ULN at screening (as defined by the manufacturer), and without any myocardial related symptoms, should have a cardiologic consultation before enrolment to rule out MI. / Corrected QT interval (QTcF) prolongation to > 470 msec (females) based on average of the screening triplicate 12-lead ECG. / History of (non-infectious) ILD / pneumonitis that required steroids, has current ILD/pneumonitis, or where suspected ILD/pneumonitis cannot be ruled out by imaging at screening. / Lung criteria: Lung-specific intercurrent clinically significant illnesses including, but not limited to, any underlying pulmonary disorder; Any autoimmune, connective tissue or inflammatory disorders (e.g., Rheumatoid arthritis, Sjogren's, sarcoidosis etc.) where there is documented, or a suspicion of pulmonary involvement at the time of randomisation; Prior pneumonectomy (complete); Uncontrolled infection requiring IV antibiotics, antivirals, or antifungals / Active primary immunodeficiency, known human immunodeficiency virus (HIV) infection, or active hepatitis B or C infection. Patients positive for hepatitis C (HCV) antibody are eligible only if polymerase chain reaction is negative for HCV RNA. Patients should be tested for HIV prior to randomisation if required by local regulations or ethics committee (EC). / Receipt of live, attenuated vaccine (mRNA and replication deficient adenoviral vaccines are not considered attenuated live vaccines) within 30 days prior to the first dose of trastuzumab deruxtecan. / Note: Patients, if enrolled, should not receive live vaccine during the study and up to 30 days after the last dose of IMP. / Known allergy or hypersensitivity to study treatment (T-DXd) or any of the study drug excipients. / History of severe hypersensitivity reactions to other monoclonal antibodies. / Pregnant or breastfeeding female patients, or patients who are planning to become pregnant.

see [Link](#):

[clinicaltrials.gov/NCT05704829](https://clinicaltrials.gov/NCT05704829)

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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

**Recruitment Status:** **RECRUITING**

**Condition:** Breast cancer  
**Primary Completion Date:** 2029-03-30  
**Intervention/ Treatment:** DRUG: Inavolisib/ Fulvestrant/ Alpelisib

**Inclusion Criteria:**  
 If pre/perimenopausal women and men treatment with luteinizing hormone-releasing hormone (LHRH) agonist therapy beginning at least 2 weeks prior to Day 1 of Cycle 1 / Histologically or cytologically confirmed adenocarcinoma of the breast that is locally advanced or metastatic and is not amenable to surgical or radiation therapy with curative intent / Documented HR +/- HER2- tumor according to American Society of Clinical Oncology/College of American Pathologists (ASCO/CAP) guidelines / Confirmation of biomarker eligibility: detection of specified mutation(s) of PIK3CA via specified test  
 Disease progression after or during treatment with a combination of CDK4/6i and endocrine therapy: <= 2 prior lines of systemic therapy in mBC setting; CDK4/6i based therapy does not need to be the last one received prior study entry; one line of chemotherapy in mBC setting allowed / Measurable or evaluable disease per Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1) / Participants for whom endocrine-based therapy is recommended and treatment with cytotoxic chemotherapy is not indicated at time of entry into the study, as per national or local treatment guidelines / Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2 / Life expectancy of > 6 months / Adequate hematologic and organ function prior to initiation of study treatment  
 see [Link:](#)

[clinicaltrials.gov/NCT05646862](https://clinicaltrials.gov/NCT05646862)

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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

**Recruitment Status:** **RECRUITING**

**Condition:** HER2-positive Breast cancer

**Primary Completion Date:** 2026-10

**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  $\geq 2$  cm or a sonographical size of  $\geq 1$  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  $\geq 18$  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)  $\geq 1.5$ / nL --Platelets  $\geq 100$ / nL and Hemoglobin  $\geq 10$  g/dL ( $\geq 6.2$  mmol/L) Hepatic function --Total bilirubin  $< \text{ULN}$  except for patients with Gilbert's syndrome who may only be included if the total bilirubin is  $\leq 3.0 \times \text{ULN}$  or direct bilirubin  $\leq 1.5 \times \text{ULN}$  --AST and ALT  $\leq 1.5 \times \text{ULN}$  and --Alkaline phosphatase  $\leq 2.5 \times \text{ULN}$  / **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  $\geq 60$  years. --Age  $< 60$  years and  $\geq 12$  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](https://clinicaltrials.gov/NCT05306041)

## 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

**Recruitment Status:** **RECRUITING**

**Condition:** Breast cancer

**Primary Completion Date:** 2026

**Intervention/ Treatment:**

### Inclusion Criteria:

Female patient has given written informed consent 2. Patient is  $\geq 18$  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  $\leq 2$ ) 8. Patient has adequate bone marrow, renal and hepatic function: a. Hemoglobin  $> 9.0$  g/dL b. Absolute neutrophil count  $\geq 1.5 \times 10^9$  /L c. Platelets  $\geq 100 \times 10^9$  /L d. Calculated creatinine clearance  $\geq 50$  mL/min as determined by the Cockcroft-Gault equation e. AST (SGOT) / ALT (SGPT) and alkaline phosphatase  $\leq 2.5 \times$  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 trial

### Exclusion Criteria:

1. 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 treatment-related 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](#):

Not available

## A Randomized, Double-Blind, Placebo-Controlled, Multi-Center, International Phase 3 Study to Determine the Preventive Effect of Denosumab on Breast cancer in Women Carrying a BRCA1 Germline Mutation

**Recruitment Status:** **RECRUITING**

**Condition:** BRCA1 Mutation, Breast cancer, Breast Diseases, Breast Neoplasms, Breast Carcinoma, Neoplasms

**Primary Completion Date:** 2027-07

**Intervention/ Treatment:** DRUG: Denosumab/ Placebo\_OTHER: Quality-of-Life Assessment

### Inclusion Criteria:

Women with a confirmed deleterious or likely deleterious BRCA 1 germline mutation (variant class 4 or 5) / Age  $\geq 25$  years and  $\leq 55$  years at randomization / No evidence of breast cancer by MRI or mammography (MG) and clinical breast examination within the last 6 months prior to randomization / No clinical evidence of ovarian cancer at randomization / Negative pregnancy test at randomization for women of childbearing potential / No preventive breast surgery planned at time of randomization / Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 / Written informed consent before any study-specific procedure is performed

### Exclusion Criteria:

Prior bilateral mastectomy / History of ovarian cancer (including fallopian and peritoneal cancer) / History of breast cancer / History of invasive cancer except for basal cell or squamous cell skin cancer or carcinoma in situ of the cervix, stage 1 papillary or follicular thyroid cancer, atypical hyperplasia or LCIS (lobular carcinoma in situ) / Pregnant or lactating women (within the last 2 months prior to randomization) / Unwillingness to use highly effective contraception method during and within at least 5 months after cessation of denosumab/placebo therapy in women of childbearing potential. (Note: Women of childbearing potential should be monitored for pregnancy prior to each denosumab/placebo injection) / Clinically relevant hypocalcemia (history and current condition), or serum calcium  $< 2.0$  mmol/L ( $< 8.0$  mg/dL) / \* Hypocalcemia defined by calcium below the normal range (a single value below the normal range does not necessarily constitute hypocalcemia, but should be 'corrected' before dosing the subject). Monitoring of calcium level in regular intervals (usually prior to investigational product [IP] administration) is highly recommended / Tamoxifen, raloxifene or aromatase inhibitor use during the last 3 months prior to randomization or for a duration of more than 3 years in total (current and prior hormone replacement therapy [HRT] is permitted) / Prior use of denosumab / Subject has a known prior history or current evidence of osteonecrosis or osteomyelitis of the jaw, or an active dental/jaw condition which requires oral surgery including tooth extraction within 3 months of enrollment / Concurrent treatment with a bisphosphonate or an anti-angiogenic agent / Any major medical or psychiatric condition that may prevent the subject from completing the study / Known active infection with hepatitis B virus or hepatitis C virus / Known infection with human immunodeficiency virus (HIV) / Use of any other investigational product (current or prior aspirin or non-steroidal anti-inflammatory drugs [NSAIDs] are permitted)

see [Link](#):

[clinicaltrials.gov/NCT04711109](https://clinicaltrials.gov/NCT04711109)

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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

**Recruitment Status:** **RECRUITING**

**Condition:** Breast cancer, Early Breast Cance

**Primary Completion Date:** 2027-04-19

**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](https://clinicaltrials.gov/NCT05774951)

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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

**Recruitment Status:** **RECRUITING**

**Condition:** Breast cancer

**Primary Completion Date:** 2026-12

**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](https://clinicaltrials.gov/NCT05232916)

Omission of Sentinel Lymph Node Biopsy in Triple-negative and HER2-positive Breast cancer Patients With Radiologic and Pathologic Complete Response in the Breast After Neoadjuvant Systemic Therapy: a Single-arm, Prospective Surgical Trial.

Recruitment Status: **RECRUITING**

Condition: Breast cancer Female, Breast cancer  
 Primary Completion Date: 2028-01  
 Intervention/ Treatment: PROCEDURE: **omission of SLNB**

**Inclusion Criteria:**

Written informed consent prior to breast-conserving surgery, including expected cooperation of the patients for follow-up, must be obtained and documented according to the European regulatory requirements / Histologically confirmed unilateral primary invasive carcinoma of the breast (core biopsy). Multifocal or multicentric tumors are allowed if breast-conserving surgery is planned. / Age at diagnosis at least 18 years / imaging techniques with estimated tumor stage between cT1-T3 prior to NAST / triple-negative or HER2-positive invasive breast cancer / clinically and sonographically tumor-free axilla prior to core biopsy (cN0/iN0) / in cases with cN0 and iN+, a negative core biopsy or fine needle aspiration (FNA) biopsy of the sonographically suspected lymph node is required / no evidence for distant metastasis (M0) / standard NAST with radiologic complete response (rCR) / planned breast-conserving surgery with postoperative external whole-breast irradiation (conventional fractionation or hypofractionation)

**Exclusion Criteria:**

History of malignancy within last 5 years, except curatively treated basalioma of the skin and carcinoma in situ of the cervix / Time since last cycle of NAST >3 months (optimal <1 month) / histologically non-invasive breast carcinoma before NAST / ER-positive (>=10% positive cells on IHC)/HER2-negative disease (triple-positive tumors are allowed) / cT4 or iT4 tumors / pregnant or lactating patients / no radiologic complete response at the end of NAST / planned total mastectomy after NAST / planned intraoperative radiotherapy (e.g. Intrabeam) or postoperative partial breast irradiation (e.g. multicatheter technique) alone; both procedures are allowed as boost techniques / male patients

see [Link](#):

[clinicaltrials.gov/NCT04101851](https://clinicaltrials.gov/NCT04101851)

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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.

**Recruitment Status:** **RECRUITING**

**Condition:** Breast cancer, Early Breast cancer

**Primary Completion Date:** 2030-03-04

**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](https://clinicaltrials.gov/NCT05952557)

## An Epidemiological, Prospective Cohort Study to Generate Real-world Evidence in Patients With HR+/HER2- Advanced Breast cancer Treated in the First Line Setting as per current SoC with an endocrine-based Palbociclib Combination Therapy

**Recruitment Status:** **RECRUITING**

**Condition:** Breast Neoplasms

**Primary Completion Date:** 2028-04-03

**Intervention/ Treatment:** DRUG: **Palbociclib + endocrine therapy**

### Inclusion Criteria:

Evidence of a personally signed and dated informed consent document indicating that the patient has been informed of all pertinent aspects of the study. / Diagnosis of HR+/HER2- locally advanced, inoperable or metastatic breast cancer. / Physician has determined that first-line treatment with palbociclib (i) in combination with an aromatase inhibitor, or (ii) in combination with fulvestrant in women who received prior endocrine therapy as per current local product label is indicated. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist. / Patients who in the opinion of the investigator are willing and able to comply with regular clinic visits as per local SoC practice at the study site. / Age of 18 years or older.

### Exclusion Criteria:

Any contraindication as per current local product label. / Prior systemic antineoplastic treatment for advanced disease. Exception: Start of first line treatment with palbociclib in combination with aromatase inhibitor or fulvestrant as per current local product label is allowed up to 4 weeks prior to inclusion. / Patients currently participating in any interventional clinical trial that includes investigational or marketed products at the time of enrollment. Note: A concomitant participation in other non-interventional/observational studies, registries and translational research networks (e.g., PRAEGNANT, OPAL) or chart reviews is allowed. / Patients who are unable to understand the nature of the study or are unwilling to sign an informed consent. Patient eligibility should be reviewed, documented, and confirmed by an

appropriately qualified member of the investigator's study team before patients are enrolled in the study.

see **Link:**

[clinicaltrials.gov/NCT05952557](https://clinicaltrials.gov/NCT05952557)

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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.

**Recruitment Status:** **RECRUITING**

**Condition:** Breast Cancer

**Primary Completion Date:** 2035-12

**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 ( $\geq$  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 ( $\geq 6 \text{ mm}^3$ , min. 10 slides, thickness:  $5 \mu\text{m}$ - $10 \mu\text{m}$ , area  $>150 \text{ mm}^2$  and 1 H&E stained slide, minimum 20% tumor content) or FFPE Block ( $\geq 6 \text{ mm}^3$  thickness:  $100 \mu\text{m}$ , area:  $>150 \text{ mm}^2$  and 1 H&E stained slide, minimum 20% tumor content) or Genomic DNA extracted from FFPE slides or block ( $\geq 600 \text{ ng}$ , Minimum volume:  $25 \mu\text{L}$ , concentration:  $20 \text{ ng}/\mu\text{L}$ , buffer:  $10 \text{ mM}$  Tris pH 8,  $1 \text{ mM}$  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  $\geq 18$  years and  $\leq 75$  years of age. / Performance status  $\leq 1$ , 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  $< 30 \text{ mL/min}$ . / Previous or concomitant cytotoxic or other systemic antineoplastic treatment that is not used for treating the primary breast cancer.

see [Link](#):

[clinicaltrials.gov/NCT05658172](https://clinicaltrials.gov/NCT05658172)

# *Gynaecological tumors*

[continue...](#) →

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.

**Recruitment Status:** **RECRUITING**

**Condition:** Epithelial Ovarian cancer

**Primary Completion Date:** 2028-06

**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  $\geq 18$  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  $\geq 16$  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 negative 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 (BRCA mutation and any histologic type) / Planned primary debulking surgery after confirmation of diagnosis and disease evaluation during laparoscopy / Body weight  $> 30$  kg / Patients must have normal organ and bone marrow function measured within 28 days prior to administration of study treatment as defined below: Haemoglobin  $\geq 10.0$  g/dL with no blood transfusion in the past 28 days / Absolute neutrophil count (ANC)  $\geq 1.5 \times 10^9/L$  / Platelet count  $\geq 100 \times 10^9/L$  / Total bilirubin  $\leq 1.5 \times$  institutional upper limit of normal (ULN) / Aspartate aminotransferase (AST), serum glutamic oxaloacetic transaminase (SGOT) / alanine aminotransferase (ALT), serum glutamic pyruvate transaminase (SGPT)  $\leq 2.5 \times$  institutional upper limit of normal unless liver metastases are present in which case they must be  $\leq 5 \times$  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  $\geq 51$  mL/min using the Cockcroft-Gault equation or based on a 24 hour urine test: / Estimated creatinine clearance  $= ((140 - \text{age [years]}) * \text{weight (kg)}) / (\text{serum creatinine (mg/dL)} * 72) (* 0.85)$  17. / Patients must have successfully contributed blood and tissue samples as per requirements.

see [Link](#):

[clinicaltrials.gov/NCT04644289](https://clinicaltrials.gov/NCT04644289)

## Niraparib vs Niraparib in Combination With Bevacizumab in Patients With Carboplatin-taxane Based Chemotherapy in Advanced Ovarian cancer (A Multicentre Randomised Phase III Trial)

**Recruitment Status:** **RECRUITING**

**Condition:** Ovarian cancer, Fallopian Tube cancer, Peritoneal cancer

**Primary Completion Date:** 2030-09

**Intervention/ Treatment:** DRUG: Carboplatin, Paclitaxel, Bevacicumb, 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  $\geq 18$  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)  $\geq 1.5 \times 10^9/L$  / Platelets (PLT)  $\geq 100 \times 10^9/L$  / Hemoglobin (Hb)  $\geq 9$  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)  $\leq 1.5$  and an Activated ProThrombin Time (aPTT)  $\leq 1.5 \times$  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  $\leq 1.5 \times$  ULN ( $\leq 2.0 \times$  ULN in patients with known Gilbert's syndrome) OR direct bilirubin  $\leq 1.0 \times$  ULN. / Aspartate aminotransferase / Serum Glutamic Oxaloacetic Transaminase (ASAT/SGOT) and Alanine aminotransferase / Serum Glutamic Pyruvate Transaminase (ALAT/SGPT)  $\leq 2.5 \times$  ULN, unless liver metastases are present, in case of liver metastases values must be  $\leq 5 \times$  ULN. / Urine dipstick for proteinuria  $< 2+$ . If urine dipstick is  $\geq 2+$ , 24 hour urine must demonstrate  $\leq 1$  g of protein in 24 hours. / Serum creatinine  $\leq 1.5 \times$  upper limit of normal (ULN) or calculated creatinine clearance  $\geq 30$  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  $\leq 140$  mmHg and diastolic BP of  $\leq 90$  mmHg for eligibility. Patients must have a BP of  $\leq 140/90$  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 ( $\geq 12$  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](https://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

**Recruitment Status:** **RECRUITING**

**Condition:** cancer of Endometrium Stage I/ cancer of Endometrium Stage II

**Primary Completion Date:** /

**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  $\beta$ -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 treatment Note: 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  $\beta$ -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](#):

Further Information: not available

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## Randomized Phase III Trial on Niraparib-TSR-042 (Dostarlimab) vs Physician's Choice CHEmotherapy in Recurrent, Ovarian, Fallopian Tube or Primary Peritoneal cancer Patients Not Candidate for Platinum Retreatment

**Recruitment Status:** **RECRUITING**

**Condition:** Ovarian cancer

**Primary Completion Date:** 2025-01

**Intervention/ Treatment:** DRUG: Niraparib/ Dostarlimab/ Pegylated liposomal doxorubicin/ Paclitaxel/ Gemcitabine/ Topotecan/ Bevacizumab

### Inclusion Criteria:

Participant must have recurrent ovarian, Fallopian tube or primary peritoneal cancer not candidate for platinum retreatment; and in particular / platinum resistant patients (platinum-free interval 1-6 months from last dose of platinum) / patients for which platinum is contraindicated because of previous allergic reactions or residual toxicity (i.e nephrotoxicity or neurotoxicity) / patients not able( in physician's opinion) to receive further platinum or not willing (in patients' opinion) to receive further platinum / Participant must have an Eastern Cooperative Oncology Group (ECOG) performance status of  $\leq 1$  / Participant must have measurable disease or evaluable based on RECIST 1.1 (patients with only CA 125 increase without evidence of disease are not included). / Participant must be  $\geq 18$  years of age / Participant must have adequate organ function / Participant receiving corticosteroids may continue as long as their dose is stable for least 4 weeks prior to initiating protocol therapy. / Participant must agree to not donate blood during the study or for 90 days after the last dose of study treatment. / Participants must agree to provide tissue from a newly obtained core or excisional biopsy of a tumor lesion. Newly-obtained is defined as a specimen obtained up to 6 weeks (42 days) prior to initiation of treatment on Day 1. / Subjects for whom newly-obtained samples cannot be provided (e.g. inaccessible or subject safety concern) may submit an archived specimen. / Female participant has a negative urine or serum pregnancy test within 7 days prior to taking study treatment if of childbearing potential and agrees to abstain from activities that could result in pregnancy from screening through 180 days after the last dose of study treatment, or is of nonchildbearing potential. / Participant must agree to not breastfeed during the study or for 180 days after the last dose of study treatment. / Participant must be able to understand the study procedures and agree to participate in the study by providing written informed consent

see **Link:**

[clinicaltrials.gov/NCT04679064](https://clinicaltrials.gov/NCT04679064)

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The objective of this multicenter randomized controlled trial is to compare a 6-month exercise and nutrition intervention (intervention group, IG) aimed at maintaining or improving physical functioning and quality of life with usual care (control group, CG) in ovarian cancer patients.

**Recruitment Status:** **RECRUITING**

**Condition:** Ovarian cancer, Malnutrition, Muscle Wasting, Fatigue

**Primary Completion Date:** 2027-07-31

**Intervention/ Treatment:** BEHAVIORAL: **combined exercise and nutrition intervention**

**Inclusion Criteria:**

Patients with FIGO II-IV stage ovarian, fallopian tube, or peritoneal carcinoma

Patients must be treated with surgery and chemotherapy

Patients receiving adjuvant or neoadjuvant chemotherapy but not yet started

**Exclusion Criteria:**

Patients with an Eastern Cooperative Oncology Group (ECOG) performance status greater than 2

Patients with inadequate German language skills

Patients with physical or mental impairments that make it impossible to perform the training programs or study procedures

**see Link:**

[clinicaltrials.gov/NCT06250686](https://clinicaltrials.gov/NCT06250686)

The objective of this multicenter randomized controlled trial is to compare a 6-month exercise and nutrition intervention (intervention group, IG) aimed at maintaining or improving physical functioning and quality of life with usual care (control group, CG) in ovarian cancer patients.

Recruitment Status: **RECRUITING**

Condition: Uterus

Primary Completion Date: /

Intervention/ Treatment: ?

see *Link*:

Further Information: ?

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

**Recruitment Status:** **RECRUITING**

**Condition:** cancer of Endometrium Stage I or II

**Primary Completion Date:** 2028-02-15

**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](https://clinicaltrials.gov/NCT03438474)

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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).

**Recruitment Status:** **ACTIVE, NOT RECRUITING**

**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

**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 therapeutic 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 therapeutic 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](https://clinicaltrials.gov/NCT04111978)

# *Germ Cell tumors*

[continue...](#) →

## 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

**Recruitment Status:** **RECRUITING**

**Condition:** Solid Tumor

**Primary Completion Date:** 2027-01

**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  $\geq 50\%$  of tumor cells expressing  $\geq 2+$  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  $\geq 18$  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](https://clinicaltrials.gov/NCT04503278)

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# *Sarcomas*

continue... →

## International Euro Ewing Trial For Treatment Optimisation In Patients With Ewing Sarcoma

**Recruitment Status:** **RECRUITING**

**Condition:** Ewing Sarcoma

**Primary Completion Date:** /

**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](https://clinicaltrialsregister.eu/2019-004153-93)

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# *Hepatocellular carcinomas*

continue... →

A Randomized, 2-arm Non-comparative Phase II Study on the Efficacy of Atezolizumab and Roche Bevacizumab (Atezo/Bev) Followed by On-demand Selective TACE (sdTACE) Upon Detection of Disease Progression or of Initial Synchronous Treatment With TACE and Atezo/Bev on 24-months Survival Rate in the Treatment of Unresectable Hepatocellular Carcinoma Patients

**Recruitment Status:** **RECRUITING**

**Condition:** Hepatocellular Carcinoma, Non-resectable

**Primary Completion Date:** 2025-03-01

**Intervention/ Treatment:** Combination Product: **Atezolizumab Injection, Bevacizumab Injection**

**Inclusion Criteria:**

Patient's signed informed consent / Age ≥18 years at time of signing Informed Consent Form / Ability to comply with the study protocol, according to investigator's judgement / Life expectancy of at least 12 weeks / HCC with histologically confirmed diagnosis / Disease that is not amenable to curative surgical and/or local ablation but eligible for TACE / ECOG Performance Status of 0 or 1 / Child-Pugh class A or B7 / Adequate hematologic and end-organ function / Negative HIV test at screening

*see [Link](#):*

[clinicaltrials.gov/NCT04224636](https://clinicaltrials.gov/NCT04224636)

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## Sequential or up-front triple treatment with durvalumab, tremelimumab and bevacizumab for non-resectable hepatocellular carcinoma (HCC) patients

**Recruitment Status:** **RECRUITING**

**Condition:** non-resectable hepatocellular carcinoma (HCC)

**Primary Completion Date:** /

**Intervention/ Treatment:** DRUG: Imfinzi/ Durvalumab/ Tremelimumab/ Bevacicumab

### Inclusion Criteria:

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. / Written informed consent and any locally required authorization / (European Union [EU] Data Privacy Directive) obtained from the patient/legal representative prior to performing any protocol-related procedures, including screening evaluations. / Age  $\geq 18$  years at the time of study entry / Body weight  $> 30$  kg. / Confirmed HCC based on histopathological findings from tumor tissues. / Must not have received prior systemic therapy for HCC. / Not eligible for locoregional therapy for unresectable HCC. For patients who progressed after locoregional therapy for HCC, locoregional therapy must have been completed  $\geq 28$  days prior to the baseline scan for the current study. / Barcelona Clinic Liver Cancer (BCLC) stage B (that is not eligible for locoregional therapy) or stage C (refer to Appendix C) / Child-Pugh Score class A. (refer to Table 8) / ECOG performance status of 0 or 1 at enrollment (refer to section 5.2.6) / Patients with HBV infection, characterized by positive hepatitis B surface antigen (HBsAg) and/or hepatitis B core antibodies (anti-HBcAb) with detectable HBV DNA ( $\geq 10$  IU/ml or above the limit of detection per local or central lab standard), must be treated with antiviral therapy, as per institutional practice, to ensure adequate viral suppression (HBV DNA  $\leq 2000$  IU/mL) prior to enrollment. Patients must remain on antiviral therapy for the study duration and for 6 months after the last dose of study medication. Patients who test positive for anti-hepatitis B core (HBc) with undetectable HBV DNA ( $< 10$  IU/ml or under the limit of detection per local or central lab standard) do not require anti-viral therapy prior to enrollment. These subjects will be tested at every cycle to monitor HBV DNA levels and initiate antiviral therapy if HBV DNA is detected ( $\geq 10$  IU/ml or above the limit of detection per local or central lab standard). HBV DNA detectable subjects must initiate and remain on antiviral therapy for the study duration and for 6 months after the last dose of study medication. / Patients with HCV infection must have confirmed diagnosis of HCV characterized by the presence of detectable HCV RNA or anti-HCV antibody upon enrollment (management of this disease is per local institutional practice). / At least 1 measurable lesion, not previously irradiated, that can be accurately measured at baseline as  $\geq 10$  mm in the longest diameter (except lymph nodes, which must have a short axis  $\geq 15$  mm) with computerized tomography (CT) or magnetic resonance imaging (MRI), and that is suitable for accurate repeated measurements as per RECIST 1.1 guidelines. A lesion which progressed after previous ablation or TACE could be measurable if it meets these criteria. / Adequate organ and marrow function, as defined below. Criteria "a," "b," "c," and "f" cannot be met with transfusions, infusions, or growth factor support administered within 14 days of starting the first dose. a. Hemoglobin  $\geq 9$  g/dL, b. Absolute neutrophil count  $\geq 1500/\mu\text{L}$ , c. Platelet count  $\geq 75000/\mu\text{L}$ , d. Total bilirubin (TBL)  $\leq 2.0 \times$  upper limit of normal (ULN), e. AST and ALT  $\leq 5 \times$  ULN, f. Albumin  $\geq 2.8$  g/dL, g. International normalized ratio (INR)  $\leq 1.6$ . Note: INR prolongation due to anticoagulants for prophylaxis (e.g., atrial fibrillation) in patients without liver cirrhosis could be exception. h. Calculated creatinine clearance  $\geq 50$  mL/minute as determined by Cockcroft-Gault (using actual body weight) or 24-hour urine creatinine clearance i. Urine dipstick for proteinuria  $< 2+$  (within 7 days prior to initiation of study treatment), unless a subsequent 24-hour urine collection demonstrates  $< 1$  g of protein in 24 hours. / Evidence of post-menopausal status or negative serum pregnancy test for female pre-menopausal patients. Women will be considered post-menopausal as described in Section 3.8. / Patient is willing and able to comply with the protocol for the duration of the study including undergoing treatment and scheduled visits and examinations including follow up. / Must have a life expectancy of at least 12 weeks

see [Link](#):

[Clinicaltrialsregister.eu/2022-001201-48](https://clinicaltrialsregister.eu/2022-001201-48)

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# *Renal cell carcinoma*

[continue...](#) →

## A Phase 1/2, Open-Label, Multicenter Study of KYV-101, an Autologous Fully-Human Anti-CD19 Chimeric Antigen Receptor T-Cell (CD19 CAR T) Therapy, in Subjects With Refractory Lupus Nephritis

**Recruitment Status:** **RECRUITING**

**Condition:** Lupus Nephritis/ Lupus Nephritis - WHO Class III/ Lupus Nephritis - WHO Class IV

**Primary Completion Date:** 2028-10

**Intervention/ Treatment:** DRUG: **Standart lymphodepletion regimen\_** BIOLOGICAL: **KYV-101 anti-CD19 CAR-T cell therapy**

### Inclusion Criteria:

Age ≥18 years / Clinical diagnosis of SLE according to 2019 European League Against Rheumatism/American College of Rheumatology (EULAR/ACR) classification criteria / Biopsy-proven proliferative LN Class III or IV according to 2018 International Society of Nephrology/Renal Pathology Society (ISN/RPS) criteria / Positive anti-nuclear antibody (ANA) (titer ≥1:80 ), anti-dsDNA (≥30 IU/mL on enzyme-linked immunosorbent assay [ELISA]), or anti-Smith at screening or by documented medical history / Up to date on recommended vaccinations, including against coronavirus disease 2019/ severe acute respiratory syndrome coronavirus 2 (Covid-19/SARS-Cov-2), per Centers for Disease Control and Prevention (CDC) or institutional guidelines for immune compromised individuals

### Exclusion Criteria:

Rapidly progressive glomerulonephritis; history of or currently active severe central nervous system (CNS) lupus, including cerebritis, cerebrovascular accident, and seizures / Prior treatment with cellular therapy (CAR-T) or gene therapy product directed at any target / History of allogeneic or autologous stem cell transplant / Evidence of active hepatitis B or hepatitis C infection / Positive serology for HIV / Primary immunodeficiency / History of splenectomy / History of stroke, seizure, dementia, Parkinson's disease, coordination movement disorder, cerebellar diseases, psychosis, paresis, aphasia, and any other neurologic disorder investigator considers would increase the risk for the subject. / Impaired cardiac function or clinically significant cardiac disease / Previous or concurrent malignancy with the following exceptions: Adequately treated basal cell or squamous cell carcinoma (adequate wound healing is required prior to screening) / In situ carcinoma of the cervix or breast, treated curatively and without evidence of recurrence for at least 3 years prior to screening / A primary malignancy which has been completely resected, or treated, and is in complete remission for at least 5 years prior to screening

**see Link:**

[clinicaltrials.gov/NCT06342960](https://clinicaltrials.gov/NCT06342960)

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# *Skin tumors*

18a

*Melanoma*

18b

*Other Neoplasms Skin*

18c

*(Uveal Melanoma)*

# *Melanoma*

continue... →

## 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

**Recruitment Status:** **RECRUITING**

**Condition:** Advanced Melanoma

**Primary Completion Date:** 2026-12

**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 allogeneic tissue/solid organ transplant

see [Link](#):

[clinicaltrials.gov/NCT05549297](https://clinicaltrials.gov/NCT05549297)

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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.

**Recruitment Status:** **RECRUITING**

**Condition:** Advanced Melanoma

**Primary Completion Date:** 2026-12-01

**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](https://clinicaltrials.gov/NCT06112314)

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

**Recruitment Status:** **RECRUITING**

**Condition:** Metastatic Melanoma, Unresectable Melanoma, Melanoma

**Primary Completion Date:** 2028-03-01

**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](https://clinicaltrials.gov/NCT05727904)

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

**Recruitment Status:** **RECRUITING**

**Condition:** Melanoma, Cutaneous Malignant

**Primary Completion Date:** 2028-01

**Intervention/ Treatment:** BIOLOGICAL: IMA203/ Nivolumab plus Relatlimab/ Lifileucel/ Nivolumab/ Pembrolizumab/ Ipilimumab

DRUG: Dacarbazine/ Temozolomide/ Paclitaxel/ Paclitaxel plus Carboplatin/ Albumin-Bound Paclitaxel

**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

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](https://clinicaltrials.gov/NCT06743126)

## A Multicenter, Randomized, Double-Blind, Active Comparator-Controlled, Adaptive Phase 2/3 Study to Evaluate the Safety and Efficacy of EIK1001 and Pembrolizumab Versus Placebo and Pembrolizumab as First-Line Therapy in Participants With Advanced Melanoma.

**Recruitment Status:** **RECRUITING**

**Condition:** Advanced Melanoma

**Primary Completion Date:** 2035-12

**Intervention/ Treatment:** DRUG: **EIK1001/ Pembrolizumab**

### 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](https://clinicaltrials.gov/NCT06697301)

#### CONTACT:

#### Dermatology

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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

**Recruitment Status:** **RECRUITING**

**Condition:** Malignant Melanoma

**Primary Completion Date:** 2028-07-22

**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](https://clinicaltrials.gov/NCT06961006)

# *Other Neoplasms Skin*

[continue...](#) →

Currently no study options

# *Uveal Melanoma*

[continue...](#) →

## 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)

**Recruitment Status:** **RECRUITING**

**Condition:** Uveal Melanoma

**Primary Completion Date:** 203112

**Intervention/ Treatment:** DRUG: Tebenafusp

**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:**

see [Link](#):

[clinicaltrials.gov/NCT06246149](https://clinicaltrials.gov/NCT06246149)

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# *Brain tumors*

[continue...](#) →

Currently no study options

continue... →

# *GIST-tumors*

continue... →

Currently no study options

continue... →

# *Side effects of oncological therapies*

[continue...](#) →

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

**Recruitment Status:** **RECRUITING**

**Condition:** Testicular cancer

**Primary Completion Date:** /

**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  $\geq 300$  mg/m<sup>2</sup> 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  $\leq 15$  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  $\leq 3$  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  $\geq 20$  dB at any single frequency or  $\geq 10$  dB at any 3 consecutive frequencies  $\leq 8$  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](mailto:dsz-hno.hno.org)

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## 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

Recruitment Status: **RECRUITING**

Condition: Drug-induced polyneuropathy

Primary Completion Date: /

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/m<sup>2</sup>) 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](https://drks.de/DRKS00022970)

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## A Phase 1, Multicenter, Open-label Study to Evaluate the Pharmacokinetics of CC-486 (Onureg®) in Subjects With Moderate or Severe Hepatic Impairment Compared With Normal Hepatic Function in Adult Subjects With Myeloid Malignancies

**Recruitment Status:** **RECRUITING**

**Condition:** Hepatic Insufficiency, Neoplasms

**Primary Completion Date:** 2025-06-01

**Intervention/ Treatment:** Drug: **ONUREG**

### Inclusion Criteria:

Documented diagnosis of Myelodysplastic syndrome, Acute myeloid leukemia, Non-acute promyelocytic leukemia, Chronic myelomonocytic leukemia, Philadelphia-negative myeloproliferative neoplasms, Myelodysplastic syndrome Myeloproliferative neoplasms overlap, Accelerated phase and blast phase Myeloproliferative neoplasms, Blastic plasmacytoid dendritic cell neoplasm according to the World Health Organization (WHO) 2016 classification / Life expectancy of  $\geq 3$  months / Stable renal function without dialysis for at least 2 months prior to investigational product administration / Has moderate or severe hepatic impairment as defined by National cancer Institute Organ Dysfunction Working Group criteria

### Exclusion Criteria:

Chemotherapy or radiotherapy within 2 weeks or 5 half-lives, whichever is longer, prior to the first day of investigational product administration / Persistent, clinically significant non-hematologic toxicities from prior therapies which have not recovered to  $< \text{Grade } 2$  / Any condition including the presence of laboratory abnormalities, which places the participant at unacceptable risk if he/she were to participate in the study / History of inflammatory bowel disease, celiac disease, prior gastrectomy, gastric bypass, upper bowel removal, or any other gastrointestinal disorder or defect that would interfere with the absorption of the investigational product and/or predispose the participant to an increased risk of gastrointestinal toxicity / Other protocol-defined inclusion/exclusion criteria apply

see [Link](#):

[clinicaltrials.gov/NCT05209295](https://clinicaltrials.gov/NCT05209295)

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# *Paediatric Oncology & Hematology*

[http://www.kinderkrebsinfo.de/e1676/e9032/index\\_ger.html](http://www.kinderkrebsinfo.de/e1676/e9032/index_ger.html)

Studienverbund Pädiatrische Hämatologie und Onkologie  
Nordwest – Gemeinsam für eine bessere Medizin.  
([studienverbund-nordwest.de](http://studienverbund-nordwest.de))

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

[continue...](#) →

# *Cross-entity studies (Basket studies)*

[continue...](#) →

## A phase 1 / 2 multiple-indication biomarker, safety, and efficacy study in advanced or metastatic Gastrointestinal cancers exploring treatment combinations with Pelareorep and Atezolizumab

**Recruitment Status:** **RECRUITING**

**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:** /

**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/mm<sup>3</sup> • Platelet count ≥7.5 × 10<sup>4</sup>/mm<sup>3</sup> • 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](http://aio-portal.de)

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## A Multicenter, Open Label, Phase III Extension Trial to Study the Long-term Safety and Efficacy in Participants With Advanced Tumors Who Are Currently on Treatment or in Follow-up in a Pembrolizumab Trial

**Recruitment Status:** **RECRUITING**

**Condition:** Solid Tumors, Hematologic Malignancies

**Primary Completion Date:** 2043-08-04

**Intervention / Treatment:** DRUG: Pembrolizumab [MK-3475(Keytruda), SoC [SOC]/ Lenvatinib

### Inclusion Criteria:

Treated on the parent pembrolizumab studies established by the Sponsor as MK-3475-587 ready. / Currently receiving pembrolizumab, pembrolizumab based combinations or lenvatinib from parent studies or in a follow-up phase. / **Additional eligibility criteria for participants who enter Second Course Phase once they are enrolled on MK-3475-587:** Has not received any anticancer systemic treatment since the last dose of pembrolizumab or a pembrolizumab-based combination in First Course Phase. / Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. / Demonstrates adequate organ function. / Have resolution of any toxic effect(s) of First Course Phase trial treatment with pembrolizumab or a pembrolizumab-based combination to Grade 1 or less (except alopecia) before trial treatment in Second Course Phase is started. If participant received major surgery or radiation therapy of >30 Gray (Gy), they must have recovered from the toxicity and/or complications of the intervention. /

A female participant is eligible to enroll if she is not pregnant, not breastfeeding, and ≥1 of the following conditions applies: A woman of childbearing potential (WOCBP) who agrees to use contraception during the study treatment period and for ≥120 days (corresponding to time needed to eliminate any study combination treatment(s) plus 30 days (a menstruation cycle) for study treatments with risk of genotoxicity. / **Additional eligibility criteria for participants who enter dosing with Lenvatinib:** / Adequately controlled blood pressure (BP) to <150/90 mmHg, with or without antihypertensive medications. / For male agrees to be abstinent from penile-vaginal intercourse OR agrees to use a highly effective contraceptive method while receiving study drug and for 7 days after the last dose of lenvatinib. / Is female and not pregnant/breastfeeding and at least one of the following applies during the study and for ≥4 days after: is not a woman of childbearing potential (WOCBP), is a WOCBP and uses highly effective contraception (low user dependency method OR a user dependent hormonal method in combination with a barrier method) or is a WOCBP who is abstinent from heterosexual intercourse.

see [Link](#):

[clinicaltrials.gov/NCT03486873](https://clinicaltrials.gov/NCT03486873)

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## 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

**Recruitment Status:** **RECRUITING**

**Condition:** Solid Tumor

**Primary Completion Date:** 2026-12-31

**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](https://clinicaltrials.gov/NCT04794699)

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.

**Recruitment Status:** **RECRUITING**

**Condition:** Malignant Neoplasms/ Carcinoma, Palliative Care

**Estimated:Completion Date:** 2025-06-30

**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](https://clinicaltrials.gov/NCT05520281)

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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)

Recruitment Status: **RECRUITING**

Condition: Cancer Survivors

Estimated/Completion Date: /

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  $\leq$  5 years / Age  $\geq$  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](https://drks.de/DRKS00034429)

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# *Cellular therapies*

[continue...](#) →

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## 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

**Recruitment Status:** **RECRUITING**

**Condition:** Solid Tumor

**Primary Completion Date:** 2027-01

**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  $\geq 50\%$  of tumor cells expressing  $\geq 2+$  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  $\geq 18$  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](https://clinicaltrials.gov/NCT04503278)

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## 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

**Recruitment Status:** **RECRUITING**

**Condition:** Refractory cancer/ Recurrent cancer/ Solid Tumor, Adult/ cancer

**Primary Completion Date:** 2028-12

**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](https://clinicaltrials.gov/NCT03689124)

# Leukemias

25a

ALL

25b

AML & MDS

25c

CLL

25d

CML

Contact at UCC Hamburg

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# *Acute lymphoblastic leukemia (ALL)*

[continue...](#) →

Contact at UCC Hamburg

Prof. Dr. med. Walter Fiedler, Tel. 040/ 7410 53919 (ALL & AML)

# 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

**Recruitment Status:** **RECRUITING**

**Condition:** Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia

**Primary Completion Date:** 2029-07-01

**Intervention/ Treatment:** DRUG: Imatinib/ Ponatinib/ Blinatumomab\_OTHER: Indication for stem cell transplantation

## Inclusion Criteria:

Male or female patients  $\geq 18$  years,  $\leq 65$  years / Philadelphia chromosome or BCR-ABL1 positive ALL / Not previously treated except with corticosteroids  $\leq 7$  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  $\leq 2$  / Signed written informed 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  $\leq 1.5 \times ULN$ . For serum lipase  $> ULN - \leq 1.5 \times ULN$ , value must be considered not clinically significant and not associated with risk factors for acute pancreatitis / Normal QTcF interval  $\leq 450$  ms for males and  $\leq 470$  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:

History of malignancy other than ALL diagnosed within 5 years (yrs) prior to start of protocol-specified therapy with defined exceptions / Contraindications against the use of Imatinib, Ponatinib, chemotherapy or Blinatumomab / Patient previously treated with tyrosine kinase inhibitors / Nursing women / Known impaired cardiac function, including any of the following: as detailed in protocol / Symptomatic peripheral vascular disease / Any history of ischemic stroke or transient ischemic attacks (TIAs) / Uncontrolled hypertriglyceridaemia / History or presence of clinically relevant CNS pathology as detailed in protocol / History or active relevant autoimmune disease / Known hypersensitivity to immunoglobulins or to any other component of the study drug formulation / Known diagnosis of human immunodeficiency virus (HIV) infection (HIV testing is not mandatory) or active infection with Hepatitis B or C / History of pancreatitis within 6 months previous to start of treatment within the trial / Treatment with any other investigational agent or participating in another trial within 30 days prior to entering this study / Inadequate hepatic functions defined as ASAT or ALAT  $> 2.5$  times the institutional upper limit of normal or  $> 5$  times ULN if considered due to leukemia / Total bilirubin  $> 1.5$ -fold the institutional upper limit unless considered to be due to organ involvement by the leukemia or to M. Gilbert / M. Meulengracht / Concurrent severe diseases which exclude the administration of therapy e.g. severe, uncontrolled acute or chronic infections / Inability to understand and/or unwillingness to sign a written informed consent

see [Link](#):

[clinicaltrials.gov/NCT06061094](https://clinicaltrials.gov/NCT06061094)

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## An Open Label, Phase I/II Study of Venetoclax in Addition to Blinatumomab Immunotherapy in Adult Patients With Relapsed/Refractory B Cell Precursor Acute Lymphoblastic Leukemia

**Recruitment Status:** **RECRUITING**

**Condition:** ALL, Recurrent, Adult

**Primary Completion Date:** 2025-06-30

**Intervention/ Treatment:** DRUG: **Blinatumomab/ Venetoclax**

### Inclusion Criteria:

Written informed consent in accordance with federal, local, and institutional guidelines. The patient must provide informed consent prior to the first screening procedure / Age  $\geq 18$  years / Eastern Cooperative Oncology Group (ECOG) performance status of  $\leq 2$  / Availability of patient-specific molecular MRD markers of immunoglobulin/T-cell receptor gene rearrangements as assessed by PCR with a sensitivity of at least  $10^{-4}$  / Diagnosis of Philadelphia negative, **CD19-positive B-precursor acute lymphoblastic leukemia according to WHO classification:** Refractory BCP-ALL to primary induction therapy, including at least three cycles of standard chemotherapy / Untreated first relapse of BCP-ALL with first remission duration  $< 12$  months or / Second or greater relapse of BCP-ALL or refractory relapse or / Relapse of BCP-ALL any time after allogeneic HSCT or / Positivity of MRD marker of immunoglobulin/T-cell receptor gene rearrangements of greater than 0.01% if in first or second remission of BCP-ALL Negative pregnancy test  $< 7$  days before first study drug in women of childbearing potential, defined as all women physiologically capable of becoming pregnant, unless they fulfil at least one of the following criteria: Post-menopausal (i.e. 12 months of natural amenorrhea or 6 months of amenorrhea with Serum FSH  $> 40$  U/ml / Post-operative after bilateral ovariectomy with or without hysterectomy / Continuous and correct application of a contraception method with a Pearl index of  $< 1\%$  (e.g. implants, depots, oral contraceptives, intrauterine device) from initial study drug administration until at least 3 months after the last dose of study drug. A hormonal contraception method must always be combined with a barrier method (e.g. condom) / Sexual abstinence / Vasectomy of the sexual partner / Ability to understand and willingness to sign a written informed consent / Willingness to participate in the registry of the German Multicenter Study Group for Adult ALL (GMALL)

**see Link:**

[clinicaltrials.gov/NCT05182385](https://clinicaltrials.gov/NCT05182385)

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## 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

**Recruitment Status:** **RECRUITING**

**Condition:** B-cell Acute Lymphoblastic Leukemia (B-ALL)

**Primary Completion Date:** 2026-06-30

**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  $\geq 5\%$  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  $\geq$  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](https://clinicaltrials.gov/NCT06137118)

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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

**Recruitment Status:** **RECRUITING**

**Condition:** Acute Lymphoblastic Leukemia

**Primary Completion Date:** 31.12.2025

**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  $\geq 5\%$  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 or any 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  $\geq 10^{-4}$ , 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  $\geq 10.000/\mu\text{L}$  (platelet transfusion allowed) / - Hemoglobin  $\geq 7.5 \text{ g/dL}$  (red blood cell transfusion allowed) /

**Cohort 2:** - Neutrophils  $\geq 1.000/\mu\text{L}$  / - Platelets  $\geq 50.000/\mu\text{L}$  / - Hemoglobin  $\geq 9 \text{ g/dL}$  / Adequate liver function defined as follows: Study Protocol GMALL-Isatuximab / - Bilirubin  $\leq 1.5 \text{ ULN}$  (unless Gilbert Meulengracht disease or classified as result of liver infiltration by investigator) / - AST and ALT  $\leq 2.5 \times \text{ULN}$  (unless classified as result of liver infiltration by investigator) / Adequate renal function defined as follows: / - Serum creatinine  $\leq 2 \times \text{ULN}$  / - Any serum creatinine level associated with a calculated creatinine clearance  $\geq 40 \text{ mL/min}$  / 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)

see [Link](#):

[Euclinicaltrials.eu:2023-507899-47-00](https://www.euclinicaltrials.eu/2023-507899-47-00)

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# *AML & MDS*

[continue...](#) →

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## Randomized Phase III Study of Standard Intensive Chemotherapy Versus Intensive Chemotherapy with CPX-351 in Adult Patients with Newly Diagnosed AML and Intermediate- or Adverse Genetics

**Recruitment Status:** **RECRUITING**

**Condition:** Acute Myeloid Leukemia

**Primary Completion Date:** 2027-06

**Intervention/ Treatment:** DRUG: Cytarabine/ Daunorubicin/ CPX-351

### Inclusion Criteria:

Patients with newly diagnosed AML and intermediate- or adverse-risk genetics (according to 2017 ELN criteria [Appendix B]), including AML with myelodysplasia-related changes (AML-MRC) and therapy-related AML according to the World Health Organization (WHO) classification / Age  $\geq 18$  years, no upper age limit / Patient considered eligible for intensive chemotherapy / Eastern Cooperative Oncology Group (ECOG) performance status  $\leq 2$  at screening / Genetic assessment in AMLSG central laboratory / Adequate renal function as evidenced by serum creatinine  $\leq 2.0 \times$  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  $\leq 1.5 \times$  upper limit of normal (ULN) unless considered due to Gilbert's disease, or leukemic involvement following approval by the Coordinating Investigator or Co-Coordinating Investigator / Aspartate aminotransferase (AST), alanine aminotransferase (ALT), and alkaline phosphatase (ALP)  $\leq 3.0 \times$  ULN, unless considered due to leukemic involvement following approval by the Coordinating Investigator or Co-Coordinating Investigator / No prior chemotherapy for acute leukemia 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  $>30 \times 10^9/L$ ); prior treatment of myelo-dysplastic syndrome with hypomethylating agents is allowed / Non-pregnant and non-nursing women of childbearing potential (WOCBP) must have a negative serum or urine pregnancy test within a sensitivity of at least 25 mIU/mL within 72 hours prior to randomization ("Women of childbearing potential" is defined as a sexually active mature woman who has not undergone a hysterectomy or bilateral oophorectomy or who has had menses at any time in the preceding 24 consecutive months) / Female patients of childbearing potential must agree to avoid getting pregnant while on therapy and for 27 weeks after the last dose of study drug / Women of childbearing potential must either commit to continued abstinence from heterosexual intercourse or apply one highly effective method of birth control (such as IUD, bilateral tubal ligation, or partner's vasectomy) in combination with one acceptable method of birth control at the same time (such as hormonal contraception or the male partner has to use a latex condom coated with spermicide lubricant or combined with spermicide gel or foam) while on therapy and for 27 weeks after the last dose of study drug. Hormonal contraception is only a highly effective method of birth control in case of combined (estrogen and progestogen containing) associated with inhibition of ovulation or progestogen-only hormonal contraception associated with inhibition of ovulation is used / Men must use a latex condom coated with a spermicide lubricant or combined with spermicide gel or foam during any sexual contact with women of childbearing potential, 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 last dose of study drug). In addition, their female partners of childbearing potential have to use a highly effective method of birth control / Able to understand and willing to sign an informed consent form (ICF)

see [Link](#):

[clinicaltrials.gov/NCT03897127](https://clinicaltrials.gov/NCT03897127)

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## 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

**Recruitment Status:** **RECRUITING**

**Condition:** Acute Myeloid Leukemia, Myelodysplastic Syndromes

**Primary Completion Date:** 2025-02-01

**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  $\geq 18$  years, no upper age limit. / Patient considered eligible for intensive chemotherapy. / Eastern Cooperative Oncology Group (ECOG) performance status  $\leq 2$  at randomization. / Molecular analysis centrally performed in AMLSG and HOVON laboratories. / Adequate renal function as evidenced by serum creatinine  $\leq 2.0 \times$  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  $\leq 2.5 \times$  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)  $\leq 3.0 \times$  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  $> 25 \times 10^9/L$ ); 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).

see Link:

[clinicaltrials.gov/NCT04628026](https://clinicaltrials.gov/NCT04628026)

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## Phase Ia/Ib study of PHD inhibitor molidustat in combination with IDH1 inhibitor ivosidenib in IDH1-mutated relapsed/refractory AML or MDS/AML patients

**Recruitment Status:** **RECRUITING**

**Condition:** Myelodysplastic syndrom

**Primary Completion Date:** ongoing

**Intervention/ Treatment:** DRUG: Ivosidenib

### Inclusion Criteria:

Age  $\geq 18$  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  $\leq 3 \times$  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),  $\leq 3.0 \times$  ULN, unless considered due to leukemic involvement of the liver, following written approval by the Principal Investigator. / Adequate renal function as evidenced by creatinine clearance  $\geq 30$  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:  $\square \geq 50$  years and in postmenopausal state  $> 1$  year or  $\square < 50$  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.

see [Link](#):

[clinicaltrialsregister.eu:2021-006895-17](https://clinicaltrialsregister.eu/2021-006895-17)

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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

**Recruitment Status:** **RECRUITING**

**Condition:** Primary or secondary AML

**Primary Completion Date:**

**Intervention/ Treatment:** DRUG: Emavusertib/ Azacitidine/ Venetoclax

### Inclusion Criteria:

Aged  $\geq 60$  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  $\geq 2$  toxicity related to treatment with azacitidine + venetoclax / **e.** not immediate candidate for allogeneic stem cell transplant / Eastern Cooperative Oncology Group (ECOG) Performance Status  $\leq 2$  / Acceptable organ function at screening as described below: / **a.** estimated creatinine clearance of  $\geq 35$  mL/minute / **b.** AST or ALT  $\leq 2 \times$  ULN / **c.** total bilirubin  $\leq 1.5 \times$  ULN or  $\leq 3 \times$  ULN in patients with documented Gilbert's syndrome / **d.** Absolute neutrophil count  $> 0.5 \times 10^9/L$  and platelets  $> 50 \times 10^9/L$  / **e.** Creatine phosphokinase  $< 2.5 \times$  ULN / **f.** Negative serum pregnancy test in women of childbearing potential (WOCP) / **g.** 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. / **h.** Ability to swallow and retain oral medications. / **i.** 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. / **j.** Willing and able to provide written informed consent and comply with the requirements of the study. / **k.** 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 promyelocytic 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  $\leq 2$ . Presence of any Grade 2 acute or chronic toxicity resulting from prior anti-cancer therapy that has not resolved to Grade  $\leq 1$  (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](https://euclinicaltrials.eu:2023-505828-58)

# *Chronic lymphocytic leukemia (CLL)*

[continue...](#) →

Contact at UCC Hamburg  
Dr. med. Minna Voigtländer, Tel. 0152 228 179 11 (CLL)

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).

**Recruitment Status:** **RECRUITING**

**Condition:** Chronic Lymphocytic Leukemia

**Primary Completion Date:** 2026-05

**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  $>30 \times 10^9/l$  / Creatinine clearance  $\geq 30\text{ml/min}$  / Adequate liver function as indicated by a total bilirubin  $\leq 2 \times$ , AST/ ALT  $\leq 2.5 \times$  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 phenprocoumon / Pregnant women and nursing mothers

see [Link](#):

[clinicaltrials.gov/NCT05197192](https://clinicaltrials.gov/NCT05197192)

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A Multicenter, Open-Label, Phase 2 Study to Evaluate the Efficacy and Safety of Venetoclax-Obinutuzumab Retreatment in Patients With Recurring Chronic Lymphocytic Leukemia

Recruitment Status: **RECRUITING**

**Condition:** Chronic Lymphocytic Leukemia (CLL)  
**Primary Completion Date:** 2025-02-22  
**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](https://clinicaltrials.gov/NCT04895436)

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# *Chronic myeloid leukemia (CML)*

[continue...](#) →

Currently no study options

continue... →

# *Myeloproliferative neoplasms (MPN)*

[continue...](#) →

## 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

**Recruitment Status:** **RECRUITING**

**Condition:** Myelofibrosis, Post-PFMR, Post-ET Myelofibrosis, Primary Myeofibrosis

**Primary Completion Date:** 2026-12-13

**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 naïve

### 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  $\geq 10$  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  $50 \times 10^9/L$   
Peripheral blood or bone marrow blast count  $\geq 10$  percent

**see Link:**

[clinicaltrials.gov/NCT06479135](https://clinicaltrials.gov/NCT06479135)

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# *Mastocytosis*

[continue...](#) →

Currently no study options

continue... →

# *Hodgkin`s disease*

[continue...](#) →

## Phase II Trial of Individualized Immunotherapy in Early-Stage Unfavorable Classical Hodgkin Lymphoma

**Recruitment Status:** **RECRUITING**

**Condition:** Classical Hodgkin Lymphoma

**Primary Completion Date:** 2026-05

**Intervention/ Treatment:** Drug: **Tislelizumab**

**Inclusion Criteria:**

Age 18-60 for the main trial cohort / Age  $\geq 61$  years and eligible for AVD as determined by CIRS-G score and investigator for the exploratory cohort / First diagnosis of treatment-naïve cHL  
Early-stage unfavorable disease (i.e. stage IA, IB and IIA with risk factors a-d, stage IIB with risk factors c-d): **1.** large mediastinal mass **2.** extranodal lesion(s) **3.** elevated erythrocyte sedimentation rate / **4.**  $\geq 3$  nodal areas

**Exclusion Criteria:**

Presence of nodular-lymphocyte predominant Hodgkin lymphoma, grey-zone lymphoma and/or central nervous system involvement of lymphoma

**see Link:**

[clinicaltrials.gov/NCT04837859](https://clinicaltrials.gov/NCT04837859)



# *Non-Hodgkin's lymphoma (NHL) + Waldenström's disease*

[continue...](#) 

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.

Recruitment Status: **RECRUITING**

Condition: Mantle Cell Lymphoma (MCL)

Primary Completion Date: /

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) / -  $\geq 60$  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  $\leq 2$  / **The following laboratory values at screening (unless related to MCL):** - Absolute neutrophil count (ANC)  $\geq 1000$  cells/ $\mu$ L / - Platelets  $\geq 75.000$  cells/ $\mu$ L / - Transaminases (AST and ALT)  $\leq 3 \times$  ULN / - Total bilirubin  $\leq 2 \times$  ULN unless other reason known (Gilbert-Meulengracht-Syndrome) / - Creatinine  $\leq 2$  mg/dL or eGFR  $\geq 50$  mL/min / - Written informed consent form according to ICH/EU GCP and national regulations / - Sexually active men with female partners of child-bearing potential 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  $\leq 65\%$  or FEV1  $\leq 65\%$ ) / - 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](https://clinicaltrialsregister.eu/2020-002935-30)

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A prospective, multicenter phase II trial investigating Gemcitabine/Oxaliplatin/Rituximab with Tafasitamab (MOR208) for patients with relapsed/refractory transformed or Aggressive Lymphoma

Recruitment Status: **RECRUITING**

Condition: Malignant B-Cell Lymphoma

Primary Completion Date: /

Intervention/ Treatment: DRUG: Tafasitamab/Gemcitabin/Oxaliplatin/Rituximab

#### Inclusion Criteria:

**Subjects meeting all of the following criteria will be considered for enrollment to the trial:-** Histologically proven diagnosis of a) diffuse large cell B-cell lymphoma, and other aggressive B-cell lymphomas according to the WHO 2016 revision (specified in detail in the protocol) / b) follicular lymphoma grade 3B and / c) transformed indolent B-cell lymphoma (not more than 20 % of the patient population) according to the WHO classification (central pathology review) / - Relapsed disease or refractory disease, at least one but no more than two prior treatment lines / - age ≥ 18 years / - No curative option available (age ≥ 65yr and/or HCT-CI Score > 2) or s.p. HDT / - At least 1 measurable tumor mass (>1.5 cm x >1.0 cm) or bone marrow infiltration / - Adequate bone marrow reserve: **a)** Platelets of at least 100 000/μl **b)** absolute neutrophil count of at least 1000/μl / - Adequate hepatic and renal function: **a)** Alanine aminotransferase (ALT) <2.5 x upper limit of normal (ULN) **b)** Aspartate aminotransferase (AST) <2.5 x upper limit of normal (ULN) **c)** Total bilirubin <1.5 x upper limit of normal (ULN) unless related to lymphoma / - Measured or calculated eGFR >50 ml/min (institutional standard) / - Eastern Cooperative Oncology Group (ECOG) performance Status ≤2, unless tumor associated and expected to improve on treatment / - Signed informed consent / - Adequate contraception (if needed)

#### Exclusion Criteria:

NS involvement (brain MRI is required only in cases of clinically suspicious involvement) / - no adequate pretreatment (R-CHOP-like, or BR for initial indolent lymphoma) / - systemic treatment within last 6 weeks, steroids for bridging are allowed / - prior allogeneic transplantation prior anti CD19 CAR T-cell therapy or prior Tafasitamab therapy / - pregnant or breast-feeding women / - severe concomitant disease (e.g. uncontrolled arterial hypertension, heart failure (NYHA III-IV), uncontrolled diabetes mellitus, pulmonary fibrosis, uncontrolled hyperlipoproteinemia) / - Prolongation of QTc interval > 450 ms, demonstrated in electrocardiogram (two separate or one in triplicate) or family history for Long QT-syndrome / - active uncontrolled infections / - HIV positivity / - Hepatitis C / - active Hepatitis B, patients with HBs-Ag positivity and no measurable HBV-DNA are eligible / - Medical or psychological condition that would not permit completion of the trial or signing of informed consent / - Diagnosed or treated for a malignancy other than NHL except: **a)** adequately treated non-melanoma skin cancer / **b)** curatively treated in-situ cancer of the cervix / **c)** ductal carcinoma in situ (DCIS) of the breast / **d)** other solid tumors curatively treated with no evidence of disease for >2 years / **e)** prostate cancer with a life expectancy of more than 2 years / - Concurrent treatment with another investigational agent or within the last 6 weeks prior to treatment initiation. Concurrent participation in non-treatment studies is not excluded. / - Known intolerance to any of the study drugs or to any drug with similar chemical structure or to any excipient present in the pharmaceutical form of the investigational medicinal product / - **see Link:**

[clinicaltrialsregister.eu/2019-002373-59](https://clinicaltrialsregister.eu/2019-002373-59)

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:** Waldenstrom Macroglobulinemia

**Primary Completion Date:** 2028-02

**Intervention/ Treatment:** DRUG: **Carfilzomib + Ibrutinib/ Ibrutinib**

**Inclusion Criteria:**

Each patient must meet **all of the following inclusion criteria** to be enrolled in this study: Proven clinicopathological diagnosis of WM as defined by consensus panel one of the Second International Workshop on WM. Histopathology has to occur before randomization within the last 4 months. In addition, pathological specimens have to be sent to the pathological reference center prior to randomization for the determination of the mutational status of MYD88 and CYCR4. Immunophenotyping will be performed in each center and saved locally. The positivity for CD20 can be assumed from any previous bone marrow immunohistochemistry or flow cytometry analysis performed up to 4 months prior to enrollment. Flow cytometry of bone marrow and blood cells will include at least one double staining and assess the disease specific expressions. / De novo and relapsed/refractory WM independent of the genotype. / Determination of mutational status of MYD88 and CXCR4. / Patients must have at least one of the following criteria to initiate treatment as partly defined by "Consensus Panel Two" recommendations from the Second International Workshop on Waldenström Macroglobulinemia: / Recurrent fever, night sweats, weight loss, fatigue (at least one of them). / Hyperviscosity. / Lymphadenopathy which is either symptomatic or bulky ( $\geq 5$  cm in maximum diameter). / Symptomatic hepatomegaly and/or splenomegaly. / Symptomatic organomegaly and/or organ or tissue infiltration. / Peripheral neuropathy due to WM. / Symptomatic cryoglobulinemia. / Cold agglutinin anemia. / IgM related immune hemolytic anemia and/or thrombocytopenia. / Nephropathy related to WM. / Amyloidosis related to WM. / Hemoglobin  $\leq 10$  g/dL (patients should not have received red blood cells transfusions for at least 7 days prior to obtaining the screening haemoglobin). / Platelet count  $< 100 \times 10^9/L$  (caused by BM infiltration of the lymphoma). / Serum monoclonal protein  $> 5$  g/dL, even with no overt clinical symptoms. / IgM serum concentration  $\geq 5$ g/dl. / and other WM associated relevant symptoms. / World Health Organization (WHO)/ECOG performance status 0 to 2. / Left ventricular ejection fraction  $\geq 40\%$  as assessed by transthoracic echocardiogram (TTE).

**Other criteria:** Age  $\geq$  than 18 years (male and female). / Life expectancy  $> 3$  months. / Baseline platelet count  $\geq 50 \times 10^9/L$ , absolute neutrophil count  $\geq 0.75 \times 10^9/L$ . (if not due to BM infiltration by the lymphoma). / Meet the following pre-treatment laboratory criteria at the Screening visit conducted within 30 days prior to randomization: / ASAT (SGPOT):  $< 3.0$  times the ULN. / ALAT (SGPT):  $< 3.0$  times the ULN. / Total Bilirubin:  $< 1.5$  times the ULN, unless clearly related to the disease (except if due to Gilbert's syndrome). / Serum creatinine:  $\leq 2$  mg/dl. / Women of childbearing potential (WOCBP) must agree to use a highly effective method of birth control for the duration of the therapy up to 6 months after end of therapy. A highly effective method of birth control is defined as those which result in a low failure rate (i.e. less than 1% per year) when used consistently and correctly such as combined (estrogen and progestogen containing) hormonal contraception associated with inhibition of ovulation (oral, intravaginal or transdermal), progestogen-only hormonal contraception associated with inhibition of ovulation (oral, injectable or implantable), intrauterine device (IUD), intrauterine hormone-releasing system (IUS), bilateral tubal occlusion, vasectomized partner or sexual abstinence. A postmenopausal state is defined as no menses for 12 months without an alternative medical cause. Contraception and pregnancy testing are required according the CTFG recommendations. / Men must agree not to father a child for the duration of therapy and 6 months after (use of a condom) and must agree to advice a female partner to use a highly effective method of birth control. Males must refrain from sperm donation for at least 6 months after the last dose of treatment.

Voluntary written informed consent in the native language of the patient before performance of any study-related procedure not part of normal medical care, with the understanding that consent may be withdrawn by the subject at any time without prejudice to future medical care.

**see Link:**

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[clinicaltrials.gov/NCT04263480](https://clinicaltrials.gov/NCT04263480)

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# *Multiple myeloma*

[continue...](#) →

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  $\leq 2$ . / 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  $\geq 0.5$  g/dL. / Urine M-protein level  $\geq 200$  mg/24h. / Serum immunoglobulin free light chain  $\geq 10$  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  $\geq$  Grade 2. / Primary refractory MM. / Participants who have previously received anti-GPRC5D or MMAE-containing treatment. / Participants who have previously received allogeneic 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](https://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 diagnostic criteria (IMWG updated criteria 2014, Rajkumar et al. 2014) with measurable disease 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, consolidation and maintenance is considered as one treatment line) and are refractory to at least one proteasome inhibitor, at least one immunomodulatory drug and at least one monoclonal anti CD38 antibody. / Subjects must have documented evidence of progressive disease during their last treatment. / **Phase 2:** Subjects must have received at least 1 prior treatment line (induction, high-dose, consolidation 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 antibody. / 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 infection(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 x10<sup>9</sup>/L (without growth factor support for the past 14 days) c. Platelet count more or equal 75 x10<sup>9</sup>/L (without growth factor or platelet stimulating agents for the past 14 days) d. Adequate hepatic function per local laboratory 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 bilirubin ≤ 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 m<sup>2</sup> 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 be 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 enrollment except for alopecia.

see [Link](#):

[clinicaltrials.gov/NCT05853965](https://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  $\leq 2$ . / 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  $\geq 0.5$  g/dL ( $\geq 5$  g/L). / Urine M-protein  $\geq 200$  mg/24 hours. / In participants without measurable serum or urine M protein, serum free light chain (FLC)  $\geq 100$  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](https://clinicaltrials.gov/NCT06158841)



# 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](https://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](https://clinicaltrials.gov/NCT05243797)

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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  $\geq 10\%$  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  $> 177$   $\mu$ mol/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  $\geq 60\%$  VI. Involved: uninvolved serum free light chain ratio  $\geq 100$  VII.  $> 1$  focal lesion on MRI examination **Presence of measurable disease:** I. Serum M-protein  $\geq 0.5$  g/dL or urine M-protein  $\geq 200$  mg/24 hours. II. Involved FLC (free light chain) level  $\geq 10$  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  $\geq 18$  and  $\leq 70$  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](https://clinicaltrials.gov/NCT05665140)

## A Randomized Phase III Trial Assessing Ixertin Versus Ixertin 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: Ixertin/ 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 ixertin / 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 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  $\geq 3$  times normal level and/or serum bilirubin  $\geq 1.5$  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  $< 30$  ml/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  $< 75 \times 10^9/l$  / Haemoglobin  $\leq 8.0$  g/dl, unless related to MM Absolute neutrophil count (ANC)  $< 1.0 \times 10^9/l$  (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](https://clinicaltrials.gov/NCT06216158)

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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  $\geq 0.5$  grams per deciliter (g/dL) by serum protein electrophoresis (sPEP) or.

ii) M-protein  $\geq 200$  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  $\geq 6$  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](https://clinicaltrials.gov/NCT05519085)

A Phase 1b/2 Dose-Escalation and Cohort-Expansion Study to Determine the Safety and Efficacy of BGB-11417 as 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:** Relapsed / 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  $\geq 500$ mg/dL, or ii. Urine protein M-spike of  $\geq 200$  mg/day, or iii. Serum free light chains  $\geq 10$  mg/dL, and an abnormal  $\kappa:\lambda$  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  $\geq 3$  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  $\geq 1$  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  $\geq 8.0$  g/dL within 7 days before first dose of study treatment, (transfusions, in accordance with institutional guidelines, are permitted) / Platelet count  $\geq 75,000/\mu\text{L}$ , within 7 days before first dose of study treatment, independent of growth factor support and transfusions / Absolute neutrophil count (ANC)  $\geq 1000/\text{mm}^3$  within 7 days before first dose of study treatment / Alanine aminotransferase (ALT) and aspartate aminotransferase (AST)  $\leq 3 \times$  upper limit of normal (ULN) and total bilirubin  $\leq 2.0 \times$  ULN (total bilirubin must be  $< 3 \times$  ULN for patients with Gilbert's syndrome)

see [Link](#):

[clinicaltrials.gov/NCT04973605](https://clinicaltrials.gov/NCT04973605)

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## 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:** Relapsed / 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](https://clinicaltrials.gov/NCT06615479)

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A Platform Study Evaluating the Safety and Efficacy of Multiple Treatments in Patients With Multiple Myeloma.  
**This substudy will explore the combination of cevostamab and lenalidomide as post-transplant maintenance therapy in participants with MM with high-risk cytogenetic features who experienced at least a partial response (PR) after induction.**

**Recruitment Status:** **RECRUITING**

**Condition:** Multiple Myeloma

**Primary Completion Date:** 2027-05-31

**Intervention/ Treatment:** DRUG: Cevostomab/ Lenalidomide

**Inclusion Criteria:**

Diagnosed with MM per International Myeloma Working Group (IMWG) criteria / Eastern Cooperative Oncology Group Performance Status of 0, or 1, or 2 / Resolution of AEs from prior anti-cancer therapy to Grade  $\leq 1$  / Agreement to undergo scheduled assessments and procedures / **Additional Inclusion Criteria for SS2:** / Completion of planned induction therapy and achievement of at least a partial response (PR) / Autologous Stem Cell Transplant (SCT) within 100 days prior to first study treatment and the absence of progressive disease / Cytogenetic high-risk features at diagnosis / Treatment with any investigational medicinal products, systemic cancer therapies, immunotherapies received previously in CO43923 (any arms) within 5 half-lives or 3 weeks whichever is the shortest / Agreement to comply with all local requirements of the lenalidomide risk minimization plan, which includes the global pregnancy prevention program / For female participants of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception / For male participants: agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom even if they have had a prior vasectomy, and agreement to refrain from donating sperm

**see Link:**

[clinicaltrials.gov/NCT05583617](https://clinicaltrials.gov/NCT05583617)

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# *Myelodysplastic Syndrome (MDS)*

[continue...](#) →

Currently no study options

continue... →

# *Anemias*

continue... →

Currently no study options

continue... →

# *Immune thrombozytopenia (ITP)*

[continue...](#) →

Currently no study options

continue... →

# *Amyloidosis*

[continue...](#) →

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](https://clinicaltrials.gov/NCT05184088)



The primary objective of this study is to access the efficacy of ALXN2220 in the treatment of adult participants with ATTR-CM by evaluating the difference between the ALXN2220 and placebo groups as assessed by the total occurrences of ACM and CV clinical events.

**Recruitment Status:** **RECRUITING**

**Condition:** Transthyretin Amyloid Cardiomyopathy

**Primary Completion Date:** 2028-07-31

**Intervention/ Treatment:** DRUG: **ALXN2220/ Placebo**

**Inclusion Criteria:**

Centrally confirmed diagnosis of ATTR-CM with either wild-type or variant TTR genotype / End-diastolic interventricular septal wall thickness  $\geq 11$  mm for women or  $\geq 12$  mm for men on echocardiography measured at Screening / NT-proBNP  $> 2000$  pg/mL at Screening / Treatment with a loop diuretic for at least 30 days prior to Screening / History of heart failure NYHA Class II-IV at Screening / Life expectancy of  $\geq 6$  months as per the Investigator's judgment / Males and females of childbearing ability must use contraception

**Exclusion Criteria:**

Known leptomeningeal amyloidosis / Known light chain (AL) or secondary amyloidosis (AA), or any other form of systemic amyloidosis / Acute coronary syndrome, unstable angina, stroke, transient ischemic attack, coronary revascularization, cardiac device implantation, cardiac valve repair, or major surgery within 3 months of Screening / Uncontrolled clinically significant cardiac arrhythmia, per Investigator's assessment / LVEF  $< 30\%$  on echocardiography / Renal failure requiring dialysis or an eGFR  $< 20$  mL/min/1.73 m<sup>2</sup> at Screening / Polyneuropathy with PND score IV

see [Link](#):

[clinicaltrials.gov/NCT06183931](https://clinicaltrials.gov/NCT06183931)

# *Primary CNS lymphomas (PCNSL)*

continue... →

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](https://clinicaltrials.gov/NCT04931368)

## 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 function**, 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/m<sup>2</sup> and methotrexate 3.5 g/m<sup>2</sup> /

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](https://clinicaltrials.gov/NCT05583071)

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## 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/m<sup>2</sup> i.v. d0; MTX 3.5 g/m<sup>2</sup> 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.

### 1. 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](https://drks.de/DRKS00024085)

# *Palliative studies*

continue... →

## 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](https://clinicaltrials.gov/NCT06097533)

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