Übersicht Klinische Studien

Klinische Abteilung für Onkologie

Medizinische Universität Wien

2. Halbjahr 2023

Kontakt für Studienanfragen

Leitende Studienkoordinatorin der Clinical Research Unit:

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Studienübersicht – Inhaltsverzeichnis

- **Programmdirektion Mammakarzinom**
  - Mammakarzinome
- **Programmdirektion Tumore des Respirationstraktes**
  - HNO Tumoren
  - Bronchuskarzinome
- **Programmdirektion Sarkome**
  - Sarkome (dzt. keine)
- **Programmdirektion Urogenitale Tumoren**
  - Nierenzellkarzinome
  - Prostatakarzinome, Hodentumoren, gynäkologische Tumoren
  - Urothelkarzinome

Studienübersicht – Inhaltsverzeichnis

- **Programmdirektion Gastrointestinale Tumoren**
  - Kolorektale Lymphome
  - Magen- und Ösophaguskarzinome
  - Pankreas- und Gallengangskarzinome
- **Programmdirektion Extranodale Lymphome**
  - Endokrin aktive Tumoren
  - Extranodale Lymphome
- **Programmdirektion Internistische Neuro-Onkologie**
  - Tumoren des Zentralen Nervensystems (dzt. keine)

Programmdirektion Mammakarzinom

ABCSG-45

- Titel: **A prospective, open, randomized, phase II study of carboplatin/ olaparib in the pre-operative treatment of patients with triple-negative primary breast cancer which exhibit the features of positive homologous recombination deficiency (HRD) Status**
- EudraCT Number: 2016-004384-39
- Principle Investigator: Bartsch
- Haupteinschlusskriterien: Early invasive triple negative breast cancer with positive HRD status
- Studienphase: II
- Sponsor: Austrian Breast & Colorectal Cancer Study Group (ABCSG)

ELEANOR

- Titel: **Neratinib in Patients With HER2+ Breast Cancer: a Multi-centric, Multi-national, Prospective, Longitudinal, Non-interventional Study in Germany and Austria**
- ClinicalTrials.gov Identifier: NCT04388384
- Principle Investigator: Bartsch
- Haupteinschlusskriterien: Patients with HR+,/HER2+ overexpressing/amplified breast cancer stage I-III
- Sponsor: Pierre Fabre Pharma GmbH

POLAR (ABCSG-49)

- Titel: **A Phase III Open-label, Multicenter, Randomized Trial of Adjuvant Palbociclib in Combination With Endocrine Therapy Versus Endocrine Therapy Alone for Patients With Hormone Receptor Positive / HER2-negative Resected Isolated Locoregional Recurrence of Breast Cancer**
- ClinicalTrials.gov Identifier: NCT03820830
- Principle Investigator: Bartsch
- Haupteinschlusskriterien: Patients with HR positive / HER2-negativeisolated locoregional recurrence of breast cancer
- Studienphase: III
- Sponsor: International Breast Cancer Study Group (IBCSG)

PERFORM / A5481152 - NIS

- Titel: **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 Standard Of Care With an EndocRine-based Palbociclib CoMbination Therapy**
- Principle Investigator: Bartsch
- Haupteinschlusskriterien:
- Sponsor: Pfizer

MK 3475-B49/KEYNOTE-B49

- Titel: **A Randomized, Double-blind, Placebo-controlled, Phase 3 Study of Pembrolizumab Plus Chemotherapy Versus Placebo Plus Chemotherapy for the Treatment of Chemotherapy-Candidate Hormone Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative (HR+/HER2-) Locally Recurrent Inoperable or Metastatic Breast Cancer (KEYNOTE-B49)**
- ClinicalTrials.gov Identifier: NCT04895358
- Principle Investigator: Bartsch
- Haupteinschlusskriterien: Patients with locally recurrent inoperable or metastatic HR+/HER2- breast cancer, which has not been previously treated with cytotoxic chemotherapy in the noncurative setting
- Studienphase: III
- Sponsor: Merck Sharp & Dohme Corp.

WO 42633 / Astefania

- Titel: **A Phase III, randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy and safety of adjuvant atezolizumab or placebo and trastuzumab emtansine for HER2-Positive Breast Cancer at high risk of recurrence following preoperative therapy**
- ClinicalTrials.gov Identifier: NCT04873362
- Principle Investigator: Bartsch
- Haupteinschlusskriterien: Histologically confirmed invasive breast carcinoma
- Studienphase: III
- Sponsor: Roch (Hoffmann-La Roche, Roche Diagnostics, La Roche Posey)

SERENA-4 / D8532C00001

- Titel: **A Randomised, Multicentre, Double-Blind, Phase III Study of AZD9833 (an Oral SERD) Plus Palbociclib Versus Anastrozole Plus Palbociclib for the Treatment of Patients With Estrogen Receptor-Positive, HER2-Negative Advanced Breast Cancer Who Have Not Received Any Systemic Treatment for Advanced Disease**
- ClinicalTrials.gov Identifier: NCT04711252
- Principle Investigator: Bartsch
- Haupteinschlusskriterien: Histologically or cytologically documented diagnosis of ER+, HER2-negative breast cancer based on local laboratory results; Previously untreated with any systemic anti-cancer therapy for their locoregionally recurrent or metastatic ER+ disease; Adequate organ and marrow function.
- Studienphase: III
- Sponsor: AstraZeneca

AGMT mBC-Register - NIS

- Titel: **Metastatic breast cancer in Austria AGMT_MBC-Registry Protocol**
- Principle Investigator: Bartsch
- Haupteinschlusskriterien: Metastatic breast cancer
- Sponsor: Arbeitsgemeinschaft Medikamentöser Tumortherapie (AGMT)

Programmdirektion Tumoren des Respirationstraktes

AC1804

- Titel: **Studying Drug Action in Pleural Effusion and Ascites: A Pilot Study**
- Principle Investigator: Füreder
- Haupteinschlusskriterien: >50 ml Aszites oder Pleuraerguss von soliden Tumoren, keine Chemotherapie innerhalb einer Woche vor Punktion
- Sponsor: Allcyte GmbH

MK-3475-689

- Titel: **A Phase III, Randomized, Open-label Study to Evaluate Pembrolizumab as Neoadjuvant Therapy and in Combination with Standard of Care as Adjuvant Therapy for Stage III-IVA Resectable Locoregionally Advanced Head and Neck Squamous Cell Carcinoma (LA HNSCC)**
- ClinicalTrials.gov Identifier: NCT03765918
- Principle Investigator: Füreder
- Haupteinschlusskriterien: Newly diagnosed Stage III/IVA, resectable, locoregionally advanced, head and neck squamous cell carcinoma
- Studienphase: III
- Sponsor: Merck Sharp & Dohme Corp.

PaceAce

- Titel: **Paclitaxel plus Cetuximab for the Treatment of recurrent and/or metastatic Head and Neck Cancer after First-Line Checkpoint Inhibitor Failure: A Multicenter, Single Arm Study**
- ClinicalTrials.gov Identifier: NCT04278092
- Principle Investigator: Füreder
- Haupteinschlusskriterien: Histologically proven locally advanced unresectable, recurrent and/or metastatic squamous cell head and neck carcinoma
- Studienphase: II
- Sponsor: Medizinische Universität Wien

CodeBreaK 100 (AMG 510)

- Titel: **A Phase 1/2, Open-label Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 510 Monotherapy in Subjects with Advanced Solid Tumors with KRAS p.G12C Mutation and AMG 510 Combination Therapy in Subjects with Advanced NSCLC with KRAS p.G12C Mutation**
- ClinicalTrials.gov Identifier: NCT03600883
- Principle Investigator: Füreder
- Haupteinschlusskriterien: Locally-advanced or metastatic solid tumors with KRAS p.G12C mutation
- Studienphase: I/II
- Sponsor: Amgen Inc.

Nanoray-312

- Titel: **A Phase 3 (Pivotal Stage) Study of NBTXR3 Activated by Investigator's Choice of Radiotherapy Alone or Radiotherapy in Combination with Cetuximab for Platinum-based Chemotherapy-ineligible Elderly Patients with Locally Advanced Head & Neck Squamous Cell Carcinoma**
- ClinicalTrials.gov Identifier: NCT04892173
- Principle Investigator: Füreder
- Haupteinschlusskriterien: For participants with oropharyngeal cancer, human papilloma virus (HPV) p16 status must be known; Has one primary tumor lesion that is amenable for intratumoral injection, as determined by the Investigato; Age ≥65 years
- Studienphase: III
- Sponsor: Nanobiotix S.A.

CA224-104

- Titel: **Phase II randomized Double-blind study of Relatlimab plus Nivolumab in combination with CHT vs. Nivolumab in combination with CHT as First Line Treatment for Participants with Stage IV or Recurrent Non-small Cell Lung Cancer (NSCLC)**
- ClinicalTrials.gov Identifier: NCT04623775
- Principle Investigator: Füreder
- Haupteinschlusskriterien: Untreated Stage IV or Recurrent Non-small Cell Lung Cancer (NSCLC)
- Studienphase: III
- Sponsor: Bristol-Myers Squibb

Enhance

- Titel: **H1-antihistamine treatment in combination with immunotherapy in patients with advanced non small cell lung cancer: A single- center phase II trial**
- EudraCT Number: 2022-001284-27
- Principle Investigator: Kiesewetter-Wiederkehr
- Haupteinschlusskriterien: Capability of understanding the purpose of the study and have given written informed consent; Histologically confirmed squamous or non-squamous NSCLC; Radiologically documented metastatic unresectable disease
- Studienphase: II
- Sponsor: Medizinische Universität Wien

AbbVie M18-868

- Titel: **Offene, randomisierte, kontrollierte globale Studie der Phase III mit Telisotuzumab-Vedotin (ABBV 399) im Vergleich zu Docetaxel bei Patienten mit vorbehandeltem, c-Met-überexprimiertem und lokal fortgeschrittenem/metastasierendem Nicht-Plattenepithel-, nicht kleinzelligem Lungenkarzinom (NSCLC) mit EGFR-Wildtyp**
- ClinicalTrials.gov Identifier: NCT04928846
- Principle Investigator: Kiesewetter-Wiederkehr
- Haupteinschlusskriterien: 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.
- Studienphase: III
- Sponsor: AbbVie Inc.

Programmdirektion Urogenitale Tumoren

CONTACT-02

- Titel: **A Phase 3, Randomized, Open-Label, Controlled Study of Cabozantinib (XL184) in Combination with Atezolizumab vs Second Novel Hormonal Therapy (NHT) in Subjects with Metastatic Castration-Resistant Prostate Cancer**
- ClinicalTrials.gov Identifier: NCT04446117
- Principle Investigator: Krainer
- Haupteinschlusskriterien: Metastatic castration-resistant prostate cancer, chemotherapy naiiv
- Studienphase: III
- Sponsor: Exelixis Inc.

Programmdirektion Gastrointestinale Tumoren

FIRE 4

- Titel: **A Randomised Study to Assess the Efficacy of Cetuximab Rechallenge in Patients With Metastatic Colorectal Cancer (RAS Wild-type) Responding to First-line Treatment With FOLFIRI Plus Cetuximab**
- ClinicalTrials.gov Identifier: NCT02934529
- Principle Investigator: Prager
- Haupteinschluskriterien: Metastatic colorectal cancer (RAS Wild-type) responding to first-line treatment with FOLFIRI plus Cetuximab
- Studienphase: III
- Sponsor: Ludwig-Maximilian Universität München

BERING-CRC

- Titel: **Encorafenib and Cetuximab in Patients With Metastatic, BRAFV600E-mutated, Colorectal Carcinoma: a Multi-centric, Multi-national, Prospective, Longitudinal, Non-interventional Study in Germany and Austria**
- ClinicalTrials.gov Identifier: NCT04673955
- Principle Investigator: Prager
- Haupteinschlusskriterien: Metastatic, BRAFV600E-mutated, colorectal carcinoma
- Sponsor: Pierre Fabre Pharma GmbH

NAPAN NL64126.018.17

- Titel: **Eine randomisierte Phase II Studie zur Zweitlinienbehandlung mit liposomalem Irinotecan und 5-FU im Vergleich zu liposomalen Irinotecan mit S1 bei Patienten mit einem metastasierten Pankreaskarzinom die eine Erstlinientherapie mit Gemcitbine erhalten haben**
- ClinicalTrials.gov Identifier: NCT03986294
- Principle Investigator: Prager
- Haupteinschlusskriterien: Able to understand and provide written informed consent; ≥ 18 years of age; Histologically or cytologically confirmed adenocarcinoma of pancreas; Documented metastatic disease, according to RECIST 1.1.; Previously treated with gemcitabine or gemcitabine containing therapy, or progression within 6 months of adjuvant gemcitabine based treatment; Adequate hepatic, renal and hematological function
- Studienphase: II
- Sponsor: Academisch Medisch Centrum - Universiteit van Amsterdam

FIGHT-302

- Titel: **A Phase 3, Open-Label, Randomized, Active-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Pemigatinib Versus Gemcitabine Plus Cisplatin Chemotherapy in First-Line Treatment of Participants With Unresectable or Metastatic Cholangiocarcinoma With FGFR2 Rearrangement**
- ClinicalTrials.gov Identifier: NCT03656536
- Principle Investigator: Prager
- Haupteinschlusskriterien: Unresectable or metastatic cholangiocarcinoma with FGFR2 rearrangement
- Studienphase: III
- Sponsor: Incyte Inc.

SKYSCRAPER-07

- Titel: **A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of Atezolizumab With or Without Tiragolumab (Anti-TIGIT Antibody) in Patients With Unresectable Esophageal Squamous Cell Carcinoma Whose Cancers Have Not Progressed Following Definitive Concurrent Chemoradiotherapy**
- ClinicalTrials.gov Identifier: NCT04543617
- Principle Investigator: Ilhan-Multu
- Haupteinschlusskriterien: Unresectable, esophageal squamous cell carcinoma
- Studienphase: III
- Sponsor: F. Hoffmann-La Roche Ltd

Programmdirektion Extranodale Lymphome

CC-99282-NHL-001 / Velocity

- Titel: **Eine multizentrische, offene Studie der Phase I zur Beurteilung der Sicherheit, Pharmakokinetik und vorläufigen Wirksamkeit eines oral erhältlichen niedermolekularen Wirkstoffes (CC-99282) allein und in Kombination mit Anti-Lymphom Wirkstoffen bei Patienten mit rezidivierten oder refraktären Non-Hodgkin-Lymphomen (R/ R NHL)**
- ClinicalTrials.gov Identifier: NCT03930953
- Principle Investigator: Raderer
- Haupteinschlusskriterien: History of Non-Hodgkin's Lymphoma (NHL) with relapsed or refractory disease
- Studienphase: I
- Sponsor: BMS / Celgene

MANGROVE

- Titel: **A Phase 3, Randomized, Open-Label, Multicenter Study Comparing Zanubrutinib (BGB-3111) Plus Rituximab Versus Bendamustine Plus Rituximab in Patients With Previously Untreated Mantle Cell Lymphoma who are Ineligible for Stem Cell Transplantation**
- ClinicalTrials.gov Identifier: NCT04002297
- Principle Investigator: Raderer
- Haupteinschlusskriterien: Histologically confirmed diagnosis of MCL with no prior systemic treatments for MCL
- Studienphase: III
- Sponsor: BeiGene

IELSG-49

- Titel: Eine **Phase-II-Studie zu Acalabrutinib in Kombination mit Tafasitamab bei Patienten/-innen mit zuvor behandelten Lymphomen der marginalen Zone (MZL)**
- ClinicalTrials.gov Identifier: NCT04646395
- Principle Investigator: Raderer
- Haupteinschlusskriterien: Previously treated patients with histologically proven marginal zone Bcell
- Studienphase: II
- Sponsor: International Extranodal Lymphoma Study Group (IELSG)

COUP-1

- Titel: **Copanlisib and Rituximab in Marginal Zone Lymphoma Patients, A Multicenter, Open Label Single-Arm Study**
- ClinicalTrials.gov Identifier: NCT03474744
- Principle Investigator: Raderer
- Haupteinschlusskriterien: Pathologicaly proven diagnosis of MZL
- Studienphase: II
- Sponsor: University Hospital Ulm

InMIND

- Titel: **A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Tafasitamab Plus Lenalidomide in Addition to Rituximab Versus Lenalidomide in Addition to Rituximab in Patients With Relapsed/Refractory (R/R) Follicular Lymphoma Grade 1 to 3a or R/R Marginal Zone Lymphoma (INCMOR 0208 301_ inMIND)**
- ClinicalTrials.gov Identifier: NCT04680052
- Principle Investigator: Raderer
- Haupteinschlusskriterien: Histologically confirmed Grade 1, 2 or 3a FL or histologically confirmed nodal MZL, slenic MZL, or extranodal MZL of the MALT
- Studienphase: III
- Sponsor: Incyte Inc.

MALT-IVA

- Titel: **A Phase II Trial of Long-Term Intravenous Treatment with Bi-Weekly Azithromycin in Patients with Gastric Lymphoma of the Mucosa Associated Lymphoid Tissue (MALT-lymphoma)**
- EudraCT Number: 2020-003152-33
- Principle Investigator: Raderer
- Haupteinschlusskriterien: Histologically confirmed gastric MALT lymphoma with measurable disease (stage I – IV)
- Studienphase: II
- Sponsor: Medizinische Universität Wien