KURZPROTOKOLL
CP-MGAH22-06

Öffentlicher Titel	Phase II/III Studie zu Margetuximab bei HER2-positivem Krebs des Magens oder Magenübergangs
Wissenschaftl. Titel	Phase 2/3 Trial to Evaluate Margetuximab in Combination With INCMGA00012 and Chemotherapy or MGD013 and Chemotherapy in Patients With Metastatic or Locally Advanced, Treatment-naïve, HER2-Positive Gastric or Gastroesophageal Junction Cancer
Kurztitel	CP-MGAH22-06
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, mehrarmig
Studienphase	Phase II/III
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): neoadjuvant
Einschlusskriterien	- Histologically confirmed diagnosis of previously untreated locally advanced unresectable or metastatic HER2+ GC or GEJ adenocarcinoma Prior systemic perioperative treatment is allowed; however the patient must have had a disease-free interval of at least 6 months from end of chemo/surgery Patients receiving perioperative anti-HER2 therapy require testing of HER2 status for eligibility Cohort A: HER2-positive (by IHC 3+) and PD-L1-positive (by IHC with 22C3 CPS >= 1%) per central review Cohort B: HER2-positive (by IHC 3+ or IHC 2+ in combination with FISH+) by local review. PD -L1 status is not required for enrollment - Availability of formalin-fixed, paraffin-embedded tumor specimen, unstained slides or contemporaneous biopsy for tumor target testing - Eastern Cooperative Oncology Group performance status of 0 or 1, verified within 3 days of Day 1 - Life expectancy >= 6 months - At least one radiographically measurable target lesion - Acceptable laboratory parameters and adequate organ function
Ausschlusskriterien	- Other malignancy that is progressing or required treatment within the past 5 years, with certain exceptions Patients with known MSI-H status - History of allogeneic stem cell or tissue/solid organ transplant - Central nervous system metastases - Clinically significant cardiovascular disease, gastrointestinal disorders, pulmonary compromise Prior neoadjuvant or adjuvant treatment with immunotherapy
Alter	18 Jahre und älter
Molekularer Marker	HER2/neu pos.
Prüfzentren	**Krankenhaus Nordwest GmbH** (Geschlossen) Institut für klinisch-onkologische Forschung Steinbacher Hohl 2-26 60488 Frankfurt am Main Prof. Dr. med. Salah-Eddin Al-Batran Tel: 069 7601 4420 albatran@khnw.de
Sponsor	MacroGenics
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT04082364 (primäres Register) EudraCT 2019-004699-21

© Clinical Trial Center Network (CTCN) Zentrale am Universitätsklinikum Frankfurt
Ohne Gewähr für Richtigkeit oder Vollständigkeit