# *KURZPROTOKOLL*
# *CP-MGAH22-06*

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| **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<br>- Availability of formalin-fixed, paraffin-embedded tumor specimen, unstained slides or contemporaneous biopsy for tumor target testing<br>- Eastern Cooperative Oncology Group performance status of 0 or 1, verified within 3 days of Day 1<br>- Life expectancy >= 6 months<br>- At least one radiographically measurable target lesion<br>- 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<br>- History of allogeneic stem cell or tissue/solid organ transplant<br>- Central nervous system metastases<br>- 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)<br>Institut für klinisch-onkologische Forschung<br>Steinbacher Hohl 2-26<br>60488 Frankfurt am Main<br>Prof. Dr. med. Salah-Eddin Al-Batran<br>Tel: 069 7601 4420<br>albatran.salah@khnw.de |
| **Sponsor** | MacroGenics |
| **Registrierung in anderen Studienregistern** | ClinicalTrials.gov NCT04082364 (primäres Register)<br>EudraCT 2019-004699-21 |