KURZPROTOKOLL
GM-IMAB-001-03

Öffentlicher Titel	Phase II Studie zu IMAB362 in Kombination mit Epirubicin/Oxaliplatin/Capecitabin (EOX) bei CLDN18.2 positivem Magen-/Ösophagusadenokarzinom
Wissenschaftl. Titel	A Randomized Phase II Multicenter, Open-Label Study Evaluating the Efficacy and Safety of IMAB362 in Combination With the EOX Regimen (Plus ZA/IL-2) as First-Line Treatment of Patients With CLDN18.2-positive Adenocarcinomas of the Stomach, the Esophagus or the Gastroesophageal Junction.
Kurztitel	GM-IMAB-001-03
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase II
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Erstlinie
Ziele	- PFS - Safety and tolerability of IMAB362 in combination with EOX - survival rate at 12 month - Overall survival (OS) - time to progression (TTP) - Objective tumor response rate (ORR) - disease control rate (DCR) - duration of response (DOR)
Einschlusskriterien	- Histologically confirmed adenocarcinoma of the stomach, the esophagus or the gastroesophageal junction - Inoperable locally advanced disease or resections with R2 outcome or recurrent or metastatic disease - CLDN18.2 expression confirmed by immunohistochemistry in paraffin embedded tumor tissue sample - Measurable and/or non-measurable disease as defined according to RECISTv1.1 - Age >= 18 years - Written Informed Consent Form - ECOG performance status (PS) 0-1 - Life expectancy > 3 months - HER2/neu negative patients and patients with HER2/neu positive status but not eligible to trastuzumab therapy in discretion of the investigator - Adequate cardiac, hepatic, renal, hematologic function
Ausschlusskriterien	- Prior severe allergic reaction or intolerance to a monoclonal antibody, to the chemotherapeutics used in this study or any excipient in the respective formulations - Previous chemotherapy for advanced disease - Previous perioperative chemotherapy with curative intention within 6 months of start of study treatment. If interval is longer than 6 months, patients are allowed - Known HIV infection or known symptomatic hepatitis (A, B, C). - Symptomatic cerebral metastases - Pregnancy or breastfeeding - Previous treatments with maximum cumulative doses of epirubicin > 500 mg/m^2 and/or other anthracyclines and anthracenediones - Known dihydropyrimidine dehydrogenase (DPD) deficiency
Alter	18 Jahre und älter
Molekularer Marker	CLDN18.2

Fallzahl	140
Sponsor	Ganymed Pharmaceuticals AG (Hauptsponsor)
Förderer	Ganymed Pharmaceuticals AG
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01630083 EudraCT 2011-005285-38