KURZPROTOKOLL
GM-IMAB-001-04

Öffentlicher Titel	IMAB362, Zoledronat und Interleukin-2 bei CLDN18.2-positivem fortgeschrittenem Magen-/Ösophagusadenokarzinom
Wissenschaftl. Titel	Multicenter, open-label, exploratory phase I pilot study to investigate safety, pharmacodynamics and pharmacokinetics of immunological effects and activity of combining multiple doses of IMAB362 with immunomodulation (zoledronic acid, interleukin-2) in patients with advanced adenocarcinoma of the stomach, the lower esophagus or the gastro-esophageal junction (PILOT)
Kurztitel	GM-IMAB-001-04
Studienart	multizentrisch, prospektiv, offen/unverblindet, Pharma-Studie, mehrarmig
Studienphase	Phase I
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Zweitlinie oder höher
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/m² and/or other anthracyclines and anthracenediones - Known dihydropyrimidine dehydrogenase (DPD) deficiency
Alter	18 Jahre und älter
Molekularer Marker	CLDN18.2
Status	Geschlossen
Fallzahl	20
Sponsor	Ganymed Pharmaceuticals AG
Förderer	Ganymed Pharmaceuticals AG
Registrierung in anderen Studienregistern	EudraCT 2011-005509-64 ClinicalTrials.gov NCT01671774

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Ohne Gewähr für Richtigkeit oder Vollständigkeit