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

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Fallzahl	140
Prüfzentren	**Krankenhaus Nordwest GmbH** (Rekrutierung beendet) Institut für klinisch-onkologische Forschung Steinbacher Hohl 2-26 60488 Frankfurt am Main Sandra Janowski Tel: 069 7601-4168 janowski.sandra@khnw.de
Sponsor	Ganymed Pharmaceuticals AG (Hauptsponsor)
Förderer	Ganymed Pharmaceuticals AG
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01630083 EudraCT 2011-005285-38