KURZPROTOKOLL
GM-IMAB-001-04

Öffentlicher Titel	IMAB362, Zoledronat und Interleukin-2 bei fortgeschrittenem Magen-/Ösophaguskarzinom
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, randomisiert, offen/unverblindet, Pharma-Studie, mehrarmig
Studienphase	Phase I
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Erstlinie Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Zweitlinie oder höher
Ziele	- Safety and Tolerability - Immune cell profile and kinetics - 1. PFS 2. ORR 3. DCR 4. DOR
Einschlusskriterien	- Histologically confirmed adenocarcinoma of the stomach, the esophagus or the gastroesophageal junction - Inoperable locally advanced disease, resections with R0, R1 or R2 outcome 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 RECIST v1.1 - Age >= 18 years - Written informed consent - ECOG performance status (PS) 0-1 - Life expectancy > 3 months
Ausschlusskriterien	- Prior hypersensitivity reaction or intolerance to one of the compounds of the study treatment - Known HIV infection or known symptomatic hepatitis (A, B, C) - Clinical symptoms of cerebral metastases - Pregnancy or breastfeeding - Patients treated with any bisphosphonate-based therapeutic for any indication during the previous year - Hypocalcemia that requires medication. Corrected (adjusted for serum albumin) serum calcium < 8 mg/dl (2 mmol/L) or > 12 mg/dL (3.0 mmol/L)
Alter	18 Jahre und älter
Molekularer Marker	CLDN18.2
Status	Geschlossen
Prüfzentren	**Krankenhaus Nordwest GmbH** 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	Ganymed Pharmaceuticals AG (Hauptsponsor)
Förderer	Ganymed Pharmaceuticals AG

Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01671774 EudraCT 2011-005509-64