

KURZPROTOKOLL
GM-IMAB-001-02

Öffentlicher Titel	Multiple Dosen IMAB362 bei fortgeschrittenem Magenkarzinom
Wissenschaftl. Titel	International, Multicenter, Open-label, Phase II Study to Investigate the Efficacy and Safety of Multiple Doses of IMAB362 in Patients With Advanced Adenocarcinoma of the Stomach or the Lower Esophagus
Kurztitel	GM-IMAB-001-02
Studienart	multizentrisch, prospektiv, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase II
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Erstlinie
Ziele	<ul style="list-style-type: none">- Efficacy and Safety- Number of Participants with adverse events as a measure of safety and tolerability- Frequency and severity of adverse events- PFS
Einschlusskriterien	<ul style="list-style-type: none">- Metastatic, refractory or recurrent disease of advanced adenocarcinoma of the stomach or the lower esophagus proven by histology- CLDN18.2 expression of the biopsy material from the cancer confirmed by immunohistochemistry- At least 1 measurable site of disease according to RECIST criteria
Ausschlusskriterien	<ul style="list-style-type: none">- Concurrent anticoagulation with vitamin K antagonists- Therapeutic doses of Heparin (prophylactic doses accepted)- Uncontrolled or severe illness- Less than 3 weeks since prior chemo-or radiation therapy- Other concurrent anticancer therapies
Alter	18 Jahre und älter
Molekularer Marker	CLDN18.2
Status	Geschlossen
Sponsor	GlaxoSmithKline
Förderer	GlaxoSmithKline
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01197885 (primäres Register) EudraCT 2009-017365-36
Therapie	IMAB362