KURZPROTOKOLL
RILOMET-1 (AMG102)

Öffentlicher Titel	Rilotumumab plus Epirubicin, Cisplatin und Capecitabin als first-line Therapie bei fortgeschrittenem MET positivem Karzinom des Magens oder gastroösophagealen Übergangs
Wissenschaftl. Titel	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo Controlled Study of Rilotumumab (AMG102) With Epirubicin, Cisplatin, and Capecitabine (ECX) as First-line Therapy in Advanced MET-Positive Gastric or Gastroesophageal Junction Adenocarcinoma
Kurztitel	RILOMET-1 (AMG102)
Studienart	multizentrisch, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Erstlinie
Ziele	- overall survival - PFS, survival rate at 12 months, time to progression, time to response, duration of response, objective response rate, disease control rate - The incidence of safety parameters including adverse events and laboratory abnormalities; the incidence of anti-rilotumumab antibody formation (immunogenicity) - PK parameters of rilotumumab and ECX (in a subset of subjects)
Einschlusskriterien	- Pathologically confirmed unresectable locally advanced or metastatic gastric or Gastroesophageal Junction (GEJ) adenocarcinoma; tumors of the distal esophagus within 5 cm of the EGJ are eligible - ECOG performance status 0 or 1 - Tumor tissue submission required - Tumor c-MetHigh immunohistochemistry status confirmed by central laboratory testing - Evaluable (measurable or non-measurable) disease by RECIST 1.1 criteria
Ausschlusskriterien	- Previous systemic therapy for locally advanced or metastatic gastric or GEJ adenocarcinoma - Less than 6 months have elapsed from completion of prior neoadjuvant or adjuvant chemotherapy or chemoradiotherapy. - Previous treatment with anthracyclines must not exceed total cumulative dose of epirubicin of 900 mg/m2 (or equivalent thereof, if a different anthracycline has been administered in the past) including doses to be administered in this study - Squamous cell histology - LVEF < 50 % as determined by either MUGA scan or ECHO
Alter	18 Jahre und älter
Molekularer Marker	MET
Status	Nachbeobachtung
Sponsor	AMGEN GmbH (Hauptsponsor)
Förderer	AMGEN GmbH
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01697072 EudraCT 2011-004923-11