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
Sponsor	AMGEN GmbH (Hauptsponsor)
Förderer	AMGEN GmbH
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01697072 EudraCT 2011-004923-11