

## **KURZPROTOKOLL** **RILOMET-1 (AMG102)**

<b>Öffentlicher Titel</b>	Rilotumumab plus Epirubicin, Cisplatin und Capecitabin als first-line Therapie bei fortgeschrittenem MET positivem Karzinom des Magens oder gastroösophagealen Übergangs
<b>Wissenschaftl. Titel</b>	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
<b>Kurztitel</b>	RILOMET-1 (AMG102)
<b>Studienart</b>	multizentrisch, randomisiert, Pharma-Studie, doppelblind, zweiarmig
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Erstlinie
<b>Ziele</b>	<ul style="list-style-type: none"><li>- overall survival</li><li>- PFS, survival rate at 12 months, time to progression, time to response, duration of response, objective response rate, disease control rate</li><li>- The incidence of safety parameters including adverse events and laboratory abnormalities; the incidence of anti-rilotumumab antibody formation (immunogenicity)</li><li>- PK parameters of rilotumumab and ECX (in a subset of subjects)</li></ul>
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- 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</li><li>- ECOG performance status 0 or 1</li><li>- Tumor tissue submission required</li><li>- Tumor c-MetHigh immunohistochemistry status confirmed by central laboratory testing</li><li>- Evaluable (measurable or non-measurable) disease by RECIST 1.1 criteria</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Previous systemic therapy for locally advanced or metastatic gastric or GEJ adenocarcinoma</li><li>- Less than 6 months have elapsed from completion of prior neoadjuvant or adjuvant chemotherapy or chemoradiotherapy.</li><li>- Previous treatment with anthracyclines must not exceed total cumulative dose of epirubicin of 900 mg/m<sup>2</sup> (or equivalent thereof, if a different anthracycline has been administered in the past) including doses to be administered in this study</li><li>- Squamous cell histology</li><li>- LVEF &lt; 50 % as determined by either MUGA scan or ECHO</li></ul>
<b>Alter</b>	18 Jahre und älter
<b>Molekularer Marker</b>	MET
<b>Sponsor</b>	AMGEN GmbH (Hauptsponsor)
<b>Förderer</b>	AMGEN GmbH
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT01697072 EudraCT 2011-004923-11