

KURZPROTOKOLL
CP12-0922

Öffentlicher Titel	Paclitaxel mit oder ohne Ramucirumab bei metastasiertem Magenkarzinom
Wissenschaftl. Titel	A Randomized, Multicenter, Double-Blind, Placebo-Controlled Phase 3 Study of Weekly Paclitaxel With or Without Ramucirumab (IMC-1121B) Drug Product in Patients With Metastatic Gastric Adenocarcinoma, Refractory to or Progressive After First-Line Therapy With Platinum and Fluoropyrimidine
Kurztitel	CP12-0922
Studienart	multizentrisch, prospektiv, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Zweitlinie oder höher
Ziele	<ul style="list-style-type: none">- Overall survival time (OS)- Progression-free survival (PFS)- Time to progressive disease (TTP)- Best overall response (BOR)- Objective response (ORR)- Serum Anti-Ramucirumab- Antibody Assessment (Immunogenicity)
Einschlusskriterien	<ul style="list-style-type: none">- Signed informed consent histologically or cytologically confirmed gastric or gastroesophageal junction adenocarcinoma- Metastatic disease or locally advanced, unresectable disease- Disease progression during or within 4 months after the last dose of the first-line therapy (platinum/fluoropyrimidine doublet with or without anthracycline)- Organs are functioning well (liver, kidney, blood)- Good performance status (ECOG 0 to 1)
Ausschlusskriterien	<ul style="list-style-type: none">- First line chemotherapy for metastatic gastric cancer other than platinum/fluoropyrimidine doublet with or without anthracycline- Previous systemic therapy with other anti-angiogenic drugs- Uncontrolled high blood pressure- Symptomatic or poorly controlled heart disease or had a heart attack or stroke within the last 6 month- Evidence of CNS metastasis at baseline
Alter	18 Jahre und älter
Status	Geschlossen
Fallzahl	663
Prüfzentren	Universitätsklinikum Frankfurt Medizinische Klinik I, Gastroenterologie/Hepatologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Prof. Dr. med. Jörg Trojan Tel: 069 6301-7860 Fax: 069 6301-6580 trojan@em.uni-frankfurt.de
Sponsor	ImClone LLC (Hauptsponsor)
Förderer	ImClone LLC
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01170663 (primäres Register) EudraCT 2010-020426-18
Therapie	Ramucirumab DP Paclitaxel