KURZPROTOKOLL
CAMN107DDE05

Öffentlicher Titel	Wirksamkeit von Nilotinib bei erwachsenen Patienten mit GIST bei Resistenz auf Imatinib und Sunitinib.
Kurztitel	CAMN107DDE05
Studienart	multizentrisch, prospektiv, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	Phase III
Erkrankung	Verdauung: Gastrointestinale Stromatumoren (GIST): Zweitlinie oder höher Verdauung: Gastrointestinale Stromatumoren (GIST): Erstlinie
Ziele	- SD - PR - CR - PFS - Time to tumor progression - OS - PFS - Duration of response
Einschlusskriterien	- Histologically confirmed diagnosis of GIST that is unresectable and/or metastatic and therefore not amenable to surgery or combined modality with curative intent. - Radiologically confirmed disease progression during imatinib therapy at a dose of at least 400 mg daily and/or radiologically confirmed disease progression during sunitinib therapy OR documented intolerance to imatinib and/or sunitinib. (Patients with prior additional investigational treatment of GIST prior to study entry can be included.) - At least one measurable site of disease on CT/MRI as defined by RECIST criteria.
Ausschlusskriterien	- Prior treatment with nilotinib. - Treatment with any cytotoxic and/or investigational cytotoxic drug 4 weeks (6 weeks for nitrosurea or mitomycin C) prior to Visit 1. - Prior or concomitant malignancies requiring active treatment other than GIST with the exception of previous or concomitant basal cell skin cancer, previous cervical carcinoma in situ. - Impaired cardiac function at visit 1 - Patients with severe and/or uncontrolled concurrent medical disease that in the opinion of the investigator could cause unacceptable safety risks or compromise compliance with the protocol e.g. impairment of gastrointestinal (GI) function, or GI disease that may significantly alter the absorption of the study drugs, uncontrolled diabetes.
Alter	18 Jahre und älter
Status	Geschlossen
Sponsor	Novartis Pharma (Hauptsponsor)
Förderer	Novartis Pharma
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01289028 (primäres Register) EudraCT 2008-000357-35
Therapie	Nilotinib