KURZPROTOKOLL
2009-02 SUN-CASE

Öffentlicher Titel	Second-line Sunitinib bei fortgeschrittenem Magen- oder Speiseröhrenkarzinom nach FOLFIRI
Wissenschaftl. Titel	A Randomized, Placebo-controlled Phase II Trial Investigating SUNITINIB Versus Placebo in Patients With Chemorefractory Advanced Adenocarcinoma of the Stomach or Lower Esophagus Treated With Chemotherapy FOLFIRI
Kurztitel	2009-02 SUN-CASE
Studienart	multizentrisch, prospektiv, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase II
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Zweitlinie oder höher
Ziele	- PFS - Objektiven Ansprechrate (komplette/partielle Remission) - Tumorkontrollrate - Dauer der Erkrankungsstabilisation - 1-Jahres-Überlebensrate - Gesamtüberlebens - Sicherheit und Verträglichkeit
Einschlusskriterien	- Signed and dated informed consent before the start of specific protocol procedures - Histological proven gastric adenocarcinoma including adenocarcinoma of the esophagogastric junction or lower esophagus - Failure of any prior chemotherapy (docetaxel and/or platinum-based chemotherapy); but patient has not previously received FOLFIRI treatment - Measurable metastatic disease according to the RECIST criteria patients aged 18 years and older - karnofsky index 100 - 70 % - Life expectancy > 12 weeks - Adequate hematological, hepatic and renal functions - At least 3 weeks from previous docetaxel- and/or platinum-based chemotherapy - Recovery from hematological side effects (CTC grade
Ausschlusskriterien	- History of another primary malignancy >3 years, with the exception of non-melanoma skin cancer and in situ carcinoma of the uterine cervix - Any prior palliative radiotherapy of the target lesions - Concurrent treatment with any other medicinal anti-cancer therapy - Prior treatment with a VEGF, VEGFR or RTK inhibitor, or prior enrolment on this study - Known allergic/hypersensitivity reaction to any of the components of the treatment - Treatment with potent CYP3A4 inhibitor within 7 days of Sunitinib/placebo dosing or with potent CYP3A4 inducer within 12 days of Sunitinib/placebo dosing

- Other serious illness or medical conditions within the last 12 months prior to study drug administration: Unstable cardiac disease despite treatment; myocardial infarction within 12 months prior to study entry; congestive heart failure NYHA grade 3 and 4; Hypertension that cannot be controlled by medication ; ongoing cardiac dysrhythmias of NCI CTCAE grade >2, atrial fibrillation of any grade, or QTc interval >450 msec for males or >470 msec for females; History of significant neurologic or psychiatric disorders including dementia or seizures; Active uncontrolled infection; History of clinically significant bleeding within the past 6 months, including hemoptysis or haematuria, or underlying coagulopathy; Active disseminated intravascular coagulation; Cerebrovascular accident including transient ischemic attack; Pulmonary embolus; Bowel obstruction or chronic diarrhoea, history or presence of inflammatory enteropathy or extensive intestinal resection; History of abdominal fistula, gastrointestinal perforation, or intra-abdominal abscess within 6 months prior to study enrolment, unless affected area has been removed surgically
- Known deficit in DPD
- Hypercalcemia not controlled by bisphosphonates
- Contraindications to the use of atropine
- Pregnant or lactating women; female patients who are pregnant or lactating or men and women of reproductive potential not willing or not able to employ an effective method of birth control/contraception to prevent pregnancy during treatment and for 3 months after discontinuing study treatment
- Known drug abuse/alcohol abuse
- Current, recent, or planned participation in an experimental treatment drug study other than this protocol
- Major surgical procedure, open biopsy or significant traumatic injury within 4 weeks before starting treatment; anticipation of need for major surgical procedure (e.g. impending bowel obstruction) during the course of the study
- History of other medical or psychiatric condition, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of an investigational drug or that might affect the interpretation of the results of the study or render the patient at high risk from treatment complications

Alter	18 Jahre und älter
Status	Geschlossen
Fallzahl	90
Sponsor	Universitätsmedizin der Johannes Gutenberg-Universität Mainz (Hauptsponsor)
	Onyx Therapeutics, Inc.
Förderer	Universitätsmedizin der Johannes Gutenberg-Universität Mainz
	Onyx Therapeutics, Inc.
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01020630 (primäres Register) EudraCT 2009-014336-38
Therapie	Sunitinib, FOLFIRI