KURZPROTOKOLL
AIO-STO-0111 / CRAD001RDE35T

Öffentlicher Titel	Phase III Studie zu Paclitaxel mit oder ohne RAD001 in Patienten mit Magenkarzinom
Wissenschaftl. Titel	A randomized, double-blind, multi-center phase III study evaluating paclitaxel with and without RAD001 in patients with gastric carcinoma who have progressed after therapy with a fluoropyrimidine/platinum-containing regimen
Kurztitel	AIO-STO-0111 / CRAD001RDE35T
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, doppelblind, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase III
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Zweitlinie oder höher

Einschlusskriterien

- Male or female patients >= 18 years old
- Histologically or cytologically confirmed and documented gastric adenocarcinoma. Adenocarcinomata of the gastro-esophageal junction will be allowed, if they have advanced disease (inoperable, recurrent or metastatic disease).
- Documented progressive disease during/after one, two or three prior treatments containing 5FU and/or its precursors or derivatives in the palliative setting
- At least one measurable or evaluable lesion by RECIST as determined by Computed Tomography (CT) Scan or Magnetic Resonance Imaging (MRI)
- ECOG performance status of 0, 1 or 2
- The following laboratory parameters: a) Absolute neutrophil count >= 1.5 x 109/L; b) Platelets >= 100 x 109/L; c) Hemoglobin (Hgb) >=9 g/dL; d) Serum creatinine <= 2 x Upper Limit of Normal (ULN)
- Adequate liver function: Total serum calcium (corrected for serum albumin) or ionized calcium >=LLN
- Women of childbearing potential must have a negative serum pregnancy test within 7 days of the first administration of study treatments and must be willing to use adequate methods of contraception during the study and for 3 months after last study drug administration.
- Written informed consent

Ausschlusskriterien

- Current treatment with any anti cancer therapy or treatment with anti cancer therapy <= 2 weeks prior to study treatment start unless rapidly progressing disease is measured
- Known hypersensitivity to RAD001 (everolimus) or to its excipients, or to other rapamycins (e.g. sirolimus, temsirolimus)
- Known prior history of hypersensitivity to paclitaxel.
- Paclitaxel refractory disease, which is defined as a disease progression under or within 12 weeks of last taxan treatment
- Chronic treatment with steroids (except for oral, topical or local injection) or another immunosuppressive agent
- Major surgery <= 2 weeks prior to starting study treatment or patients who have not recovered from such therapy
- Lack of resolution of all acute toxic effects (excluding alopecia) of prior chemotherapy, prior radiotherapy, or surgical procedure to National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) grade <= 1. Note: Neuropathy due to prior chemotherapy is allowed.
- Unstable CNS disease
- Requiring increasing doses of steroids to maintain stable neurological status
- Deteriorating / changing neurological status
- Known history of HIV seropositivity (HIV testing is not mandatory) or Hepatitis B or C.

	- Active, bleeding diathesis or on oral anti-vitamin K medication (except low dose warfarin, as long as the INR is <= 2.0) - Any other severe and/or uncontrolled medical conditions
Alter	18 Jahre und älter
Status	Geschlossen
Prüfzentren	**Krankenhaus Nordwest GmbH** Institut für klinisch-onkologische Forschung Steinbacher Hohl 2-26 60488 Frankfurt am Main Prof. Dr. med. Salah-Eddin Al-Batran Tel: 069 7601 4420 albatran@khnw.de **Universitätsklinikum Frankfurt** Medizinische Klinik I, Gastroenterologie/Hepatologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Dr. Silke Flebbe Tel: 069 6301-87769 Fax: 069 6301-6580 flebbe@med.uni-frankfurt.de
Sponsor	Krankenhaus Nordwest
Förderer	Novartis Pharma
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01248403 EudraCT 2009-018092-14