PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

An Open-label, Randomized, Controlled, Multicenter, Phase I/II Trial Investigating 2 EMD 525797 Doses in Combination With Cetuximab and Irinotecan Versus Cetuximab and Irinotecan Alone, as Second-line Treatment for Subjects With K-ras Wild Type Metastatic Colorectal Cancer.

Trial Acronym

POSEIDON

URL of the trial

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Brief Summary in Lay Language

The purpose of this study is to assess the safety and clinical activity of the experimental drug EMD 525797 (study drug), a monoclonal antibody targeting α v integrins, in combination with irinotecan and cetuximab in K-ras wildtype metastatic colorectal cancer patients.

Brief Summary in Scientific Language

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Organizational Data

- DRKS-ID: **DRKS00003672**
- Date of Registration in DRKS: **2012/05/03**
- Date of Registration in Partner Registry or other Primary Registry: **2009/10/19**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT01008475 (ClinicalTrials.gov)**
- Sponsor-ID: **EMR62242-004 (Merck KGaA)**

Health condition or Problem studied

- Free text: **Metastatic Colorectal Cancer**
- ICD10: **C20 - Malignant neoplasm of rectum**
- ICD10: **C18 - Malignant neoplasm of colon**
- ICD10: **C21 - Malignant neoplasm of anus and anal canal**

Interventions/Observational Groups

- Arm 1: **Biological: EMD 525797, Irinotecan and Cetuximab**
- Arm 2: **Biological: EMD 525797, Irinotecan and Cetuximab**
- Arm 3: **Drug: Irinotecan and Cetuximab**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **I-II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Primary endpoint of Safety Part: Number and proportion of subjects experiencing DLTs (dose limiting toxicity) using the NCI-CTCAE Version 3.0 in each dose level over the first 2 weeks after first drug intake; time frame: the first 2 weeks after first drug intake (14 days)
- Primary endpoint of Randomised Part: The Progression free survival (PFS) hazard ratio of each experimental treatment over standard of care arm.; time frame: Time from randomization until radiological progressive disease confirmed by investigator or all cause death

Secondary Outcome

- To further evaluate the efficacy of 2 EMD 525797 doses with respect to overall survival (OS) time; time frame: Time from randomization to death
- To further evaluate the efficacy of 2 EMD 525797 doses with respect to time to progression (TTP); time frame: Time from randomization to progression
- To further evaluate the efficacy of 2 EMD 525797 doses with respect to tumor response (RECIST criteria [Version 1.0]); time frame: Time from randomization to confirmed response
- To further evaluate the efficacy of 2 EMD 525797 doses with respect to time to treatment failure (TTF); time frame: Time from randomization to treatment discontinuation for any reason

Countries of recruitment

- BE **Belgium**
- BG **Bulgaria**
- CY **Cyprus**
- CZ **Czech Republic**
- DE **Germany**
- GR **Greece**
- HU **Hungary**
- IL **Israel**
- PL **Poland**
- RU **Russian Federation**
- ES **Spain**
- UK **United Kingdom**

Locations of Recruitment

- **Research Site, Dresden**
- **Research Site, Essen**
- **Research Site, Hamburg**
- **Research Site, Heilbronn**
- **Research Site, Landshut**
- **Research Site, Leipzig**
- **Research Site, Munich**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2009/10/31**
- Target Sample Size: **228**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Subjects with histologically confirmed k ras wildtype (WT) colorectal carcinoma (CRC) with documented distant metastasis;

- Prior oxaliplatin/fluoropyrimidine-containing regimen for the first-line treatment of metastatic disease;

- Failed an oxaliplatin regimen for metastatic colorectal carcinoma (mCRC). Failure is defined as either progressive disease (PD) (clinical or radiologic) within 6 months of the last dose of any agent of an oxaliplatin-based regimen or intolerance to an oxaliplatin regimen. Intolerance to an oxaliplatin regimen is defined as discontinuation due to any of the following: severe allergic reaction, persistent severe neurotoxicity, or delayed recovery from toxicity preventing retreatment;

- At least 1 radiographically documented measurable lesion in a previously non irradiated area according to Response Evaluation Criteria In Solid Tumors (RECIST, Version 1.0), i.e., this lesion must be adequately measurable in at least 1 dimension (longest diameter to be recorded) as ≥2 cm by conventional techniques or ≥1 cm by spiral CT scan;

- Eastern Cooperative Oncology Group (ECOG) performance status 0 1, or KPS ≥80%;

- Absolute Neutrophil Count(ANC) ≥1.5 x 10E9/L;

- Platelets ≥100 x 10E9/L;

- Hemoglobin ≥9 g/dL (without transfusions);

- Bilirubin ≤1.5 x ULN;

- ASAT ≤5 x ULN and ALAT ≤5 x ULN;

- Serum creatinine ≤1.25 x Upper limit of normal (ULN) and/or creatinine clearance ≥50 ml/min;

- International Nationalized Ratio (INR), and partial thromboplastin time (PTT) within normal limits;

- Sodium and potassium within normal limits or ≤10% above or below (supplementation permitted);

Exclusion criteria

- Previous treatment with any inhibitor of Epidermal Growth Factor Receptor (EGFR);

- Known brain metastasis and/or leptomeningeal disease;

- Radiotherapy (except localized radiotherapy for pain relief), major surgery, or any investigational drug in the 30 days before the start of trial treatment entry; planned major surgery during the trial;

- Concurrent chronic systemic immune or hormone therapy not indicated in this trial protocol (except for physiologic replacement; steroids up to 10 mg of prednisone equivalent or topical and inhaled steroids are allowed);

- Clinically relevant coronary artery disease (New York Heart Association [NYHA] functional angina classification III/IV), congestive heart failure (NYHA III/IV), clinically relevant cardiomyopathy, history of myocardial infarction in the last 12 months, or high risk of uncontrolled arrhythmia;

- Uncontrolled hypertension defined as systolic blood pressure ≥160 mmHg and/or diastolic blood pressure ≥100 mmHg under resting conditions;

- History of coagulation disorder associated with bleeding or recurrent thrombotic events;

- History of recent peptic ulcer disease (endoscopically proven gastric, duodenal or

esophageal ulcer) within 6 months of trial treatment start;

- Chronic inflammatory bowel disease, or acute/chronic ileus;

- Active infection (requiring i.v. antibiotics), including active tuberculosis, active or chronic Hepatitis B or C, or ongoing HIV infection

Addresses

■ **Primary Sponsor**

Merck KGaA

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

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■ **Contact for Public Queries**

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E-mail: **[---]***
URL: **[---]***

Sources of Monetary or Material Support

■ **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

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Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 4
- Last processed date by ClinicalTrials.gov: 2013/10/30

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*