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

Trial Description

Title

An Open Label, Single Arm Trial to Characterize Patients With Metastatic Renal Cell Carcinoma Treated With Everolimus After Failure of the First VEGF-targeted Therapy

Trial Acronym

MARC-2

URL of the trial

[---]*

Brief Summary in Lay Language

A single arm, open-label, multi-center phase IV clinical trial for patients with metastatic renal cell carcinoma, who have progressed on or after the first VEGF-targeted therapy.

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00004020**
- Date of Registration in DRKS: **2013/06/07**
- Date of Registration in Partner Registry or other Primary Registry: **2010/12/23**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2010-021370-11**
-

Primary Registry-ID: **NCT01266837 (ClinicalTrials.gov)**

- Sponsor-ID: **CRAD001LDE36T (iOMEDICO AG)**
- Other Secondary-ID: **2010-021370-11**

Health condition or Problem studied

- Free text: **Metastatic Renal Cell Carcinoma**
- Free text: **Failure of Exactly One Prior VEGF-targeted Therapy**
- ICD10: **C64 - Malignant neoplasm of kidney, except renal pelvis**

Interventions/Observational Groups

- Arm 1: **Drug: Everolimus**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Rate of patients progression free 6 months after start of study treatment; time frame: 2 years after LPI

Secondary Outcome

- Relation between biomarkers and clinical benefit (response, stable disease and progression/ no clinical benefit) of patients; time frame: 2 years after LPI

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Charitè Campus Benjamin Franklin, Berlin**
- **Klinik und Poliklinik für Urologie , Universitätsklinikum Carl Gustav Carus der Technischen Universität Dresden, Dresden**
- **Urologie - Waldkrankenhaus St. Marien, Erlangen**
- **Klinik für Innere Medizin (Tumorforschung), Universitätsklinikum Essen, Essen**
- **Zentrum Innere Medizin, Medizinische Hochschule Hannover, Hannover**
- **Klinik für Urologie und Kinderurologie, Universitätsklinikum des Saarlandes, Homburg**
- **Klinik für Urologie, Universitätsklinikum Jena, Jena**
- **5. Medizinische Klinik, Klinikum Nürnberg, Nürnberg**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2011/03/31**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **[---]***

Inclusion Criteria

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

Additional Inclusion Criteria

1. Provide written informed consent

2. Aged 18 years and above

3. Histologically or cytologically confirmed predominantly clear cell renal cell carcinoma

4. Metastatic disease documented by CT or MRI (histological confirmation

not mandatory but wishful)

5. Patients with or without nephrectomy (partial or total)

6. Patients with at least one measurable lesion at baseline according to RECIST criteria 1.1

7. Failure of exactly one prior VEGFR-TKI therapy (e.g. sunitinib, sorafenib, pazopanib) for metastatic renal cell carcinoma

8. ECOG 0-2

9. Hemoglobin ≥ 9.0 g/dL

10. Platelet count ≥75,000/µL

11. Absolute neutrophil count ≥1,5x109/l

12. Serum creatinine < 2.5 x ULN

13. Liver function: Serum bilirubin ≤ 1.5 x ULN, AST or ALT ≤ 2.5 x ULN. Patients with suspected liver metastasis: AST and ALT ≤ 5x ULN

14. Able to swallow the study drug whole as a tablet

15. Expected life expectancy of at least 6 months

16. Women of childbearing potential must have had a negative serum pregnancy test within 14 days prior to the administration of the study treatment or must have a documented condition that prohibits pregnancy (e.g. hysterectomy, post-menopausal).

Exclusion criteria

1. Patients who have received >1 prior VEGFR-TKI therapy or prior therapy with bevacizumab +/- interferon.

2. VEGFR-TKI therapy within 14 days prior to start of study drug

3. Patients who have previously received systemic mTOR inhibitors (sirolimus, temsirolimus, everolimus).

4. Patients with a known hypersensitivity to everolimus or other rapamycin (sirolimus, temsirolimus) or to its excipients.

5. Any condition which, in the opinion of the investigator, would preclude participation in this trial

6. Patients within 4 weeks post-major surgery (e.g., intra-thoracic, intra-abdominal or intrapelvic), open biopsy, or significant traumatic injury to avoid wound healing complications. Minor procedures and percutaneous biopsies or placement of vascular access device require 7 days prior to study entry.

7. Patients who had radiation therapy within 4 weeks prior to start of study treatment. Palliative radiotherapy to bone lesions within 2 weeks prior to study treatment start.

8. Patients in anticipation of the need for major surgical procedure during the course of the study.

9. Patients with a serious non-healing wound, ulcer, or bone fracture.

10. Patients with a history of seizure(s) not controlled with standard medical therapy.

11. History or clinical evidence of central nervous system (CNS) metastases. Subjects who have previously-treated CNS metastases (surgery ± radiotherapy, radiosurgery, or gamma knife) and meet all 3 of the following criteria are eligible:

1. are asymptomatic and,

2. have had no evidence of active CNS metastases for ≥ 3 months prior to enrolment (inactive/controlled CNS metastases are allowed) and,

3. have no requirement for steroids or enzyme-inducing anticonvulsants (e.g. carbamazepine, phenobarbital, phenytoin)

12. Patients receiving chronic systemic treatment with corticosteroids (dose of > 10 mg/day methylprednisone equivalent) or another immunosuppressive agent. Inhaled and topical steroids are acceptable.

13. Poorly controlled diabetes as defined by fasting serum glucose >2.0 x ULN.

14. Impaired liver function classified as Child-Pugh class C.

15. Active (acute or chronic) or uncontrolled infection of bacterial, mycotic or viral genesis.

16. Liver disease such as chronic active hepatitis or chronic persistent

hepatitis.

17. Patients with a known history of HIV seropositivity.

18. Patients with active bleeding disorders.

19. Patients who have any severe and/or uncontrolled medical conditions or other conditions within the past 12 months that could affect their participation in the study such as cardiac angioplasty or stenting, unstable angina pectoris, symptomatic peripheral vascular disease, symptomatic congestive heart failure (NYHA II, III, IV), myocardial infarction ≤ 6 months prior to first study treatment, serious uncontrolled cardiac arrhythmia, any disorders that impair the ability to evaluate the patient or for the patient to complete the study.

20. Patients who have a history of another primary malignancy and off treatment for ≤ 3 years, with the exception of non-melanoma skin cancer and carcinoma in situ of the uterine cervix or breast, and localized cancer of the bladder (T1) and prostate (T1 - T2).

21. Female patients who are pregnant or breast feeding.

22. Men and women of reproductive potential who are not using highly effective birth control methods. Oral contraceptives for female patients and barrier contraceptives are not acceptable. For definition of highly effective birth control methods please refer to section 12.3.6 of this protocol.

23. Patients who are using other investigational agents or who had received investigational drugs ≤ 2 weeks prior to study treatment start.

24. Patients unwilling or unable to comply with the protocol.

25. Exclusion criteria for MRI: intracorporal metal (e.g. incompatible heart valves, pacemakers), contrast media allergy, claustrophobia

Addresses

■ **Primary Sponsor**

iOMEDICO AG

Primary Sponsor

iOMEDICO AG

Telephone: **[---]***
Fax: **[---]***
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- **Contact for Scientific Queries**

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Michael Staehler, Dr. med

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- **Collaborator, Other Address**

Novartis

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

Sources of Monetary or Material Support

- **[---]***

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

Telephone: **[---]***
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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: 7
- Last processed date by ClinicalTrials.gov: 2016/01/14
Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.