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

Trial Description

Title

A Phase II, Open Label, Randomized Study of GDC-0980 Versus Everolimus in Patients With Metastatic Renal Cell Carcinoma Who Have Progressed on or Following VEGF-Targeted Therapy

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Study PIM4973g is a multicenter, international, open-label Phase II trial. Patients with metastatic renal cell carcinoma who have progressed on or after Vascular endothelial growth factor- (VEGF) targeted therapy will be randomized.

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00006510**
- Date of Registration in DRKS: **2015/04/14**
- Date of Registration in Partner Registry or other Primary Registry: **2011/09/26**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT01442090 (ClinicalTrials.gov)**

- Sponsor-ID: **PIM4973g (Genentech)**
- Other Secondary-ID: **GO00885**

Health condition or Problem studied

- Free text: **Renal Cell Carcinoma**
- ICD10: **C64 - Malignant neoplasm of kidney, except renal pelvis**

Interventions/Observational Groups

- Arm 1: **Drug: Everolimus**
- Arm 2: **Drug: GDC-0980**

Characteristics

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

Primary Outcome

- Progression-free survival (PFS), defined as the time from randomization to disease progression, as assessed by the investigator using Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1, or death from any cause on study; time frame: Up to 23 months

Secondary Outcome

- Objective tumor response as assessed by the investigator using RECIST v1.1; time frame: Up to 23 months
- Duration of objective response, defined as the time from first observation of an objective tumor response until first observation of disease progression as assessed by the investigator using RECIST v1.1; time frame: Up to 23 months
- Overall survival (OS), defined as the time from treatment initiation until death

from any cause; time frame: Up to 36 months

Countries of recruitment

- US **United States**
- FR **France**
- DE **Germany**
- ES **Spain**
- UK **United Kingdom**

Locations of Recruitment

- **Berlin**
- **Hannover**
- **München**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2011/10/31**
- Target Sample Size: **85**
- 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

- Histologically or cytologically documented, incurable metastatic renal cell carcinoma
with clear-cell component that progressed on or within 6 months of stopping
VEGF-targeted therapy

- Disease that is measurable per RECIST v1.1

- Karnofsky performance status of >= 70%

- Adequate hematologic and end organ function

- For female patients of childbearing potential and male patients with partners of childbearing potential, agreement to use two effective forms of contraception and to continue its use for the duration of the study

Exclusion criteria

- Any anti-cancer therapy, including chemotherapy, biologic or other targeted therapy, herbal therapy, hormonal therapy, or radiotherapy, within 5 half-lives (for systemic agents) or 2 weeks, whichever is shorter, prior to Day 1

- Requirement for chronic antihyperglycemic therapy

- Current dyspnea at rest or any requirement for supplemental oxygen therapy to perform activities of daily living

- Previously established diagnosis of pulmonary fibrosis of any cause

- Current unstable angina

- History of myocardial infarction within 6 months prior to Day 1

- New York Heart Association (NYHA) Class II or greater congestive heart failure

- History of malabsorption syndrome or other condition that would interfere with enteral absorption

- Clinically significant history of liver disease, including cirrhosis and current alcohol abuse

- Presence of positive test results for hepatitis B or hepatitis C

- Known HIV infection

- Active infection requiring IV antibiotics

- Active autoimmune or inflammatory disease that is not controlled by nonsteroidal anti-inflammatory drugs

- Pregnancy, lactation, or breastfeeding

- Current severe, uncontrolled systemic disease

- Major surgical procedure or significant traumatic injury within 28 days prior to Day

1 or anticipation of the need for major surgery during the course of study treatment

- Uncontrolled hypercalcemia

- Uncontrolled hypomagnesemia or hypokalemia

- Leptomeningeal disease as a manifestation of cancer

- History of other malignancies </= 5 years of Day 1 except for tumors with a negligible risk for metastasis or death, such as adequately controlled basal cell carcinoma or squamous cell carcinoma of the skin or carcinoma in situ of the cervix

- Untreated or active central nervous system (CNS) metastases

- Need for current chronic corticosteroid therapy (>/= 10 mg of prednisone per day or an equivalent dose of other anti-inflammatory corticosteroids for > 7 days) or use of other immunosuppressants

Addresses

■ **Primary Sponsor**

Genentech, Inc.

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

■ **Contact for Scientific Queries**

Genentech, Inc.
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Clinical Trials

Contact for Public Queries

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URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

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

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

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/07/01**

Trial Publications, Results and other documents