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Trial record **2 of 3** for: axitinib | Completed | renal cell carcinoma | United States | Adult, Senior

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Anti-angiogenesis Agent AG-013736 in Patients With Metastatic Renal Cell Carcinoma

This study has been completed.

Sponsor:
Pfizer

Information provided by (Responsible Party):
Pfizer

ClinicalTrials.gov Identifier:
NCT00076011

First received: January 12, 2004
Last updated: June 20, 2012
Last verified: June 2012
History of Changes

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Purpose

The primary purpose of this protocol is to determine the activity of **AG 013736** in patients with metastatic renal cell cancer who have received 1 prior cytokine-based therapy.

Condition	Intervention
Kidney Neoplasms	Drug: Vascular Endothelial Growth Factor Receptor [VEGFR] and Platelet-Derived Growth Factor Receptor [PDGFR] inhibitor

Study Type: Interventional
Study Design: Allocation: Non-Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Phase 2 Study of **AG 013736** as Second-Line Treatment in Patients With Metastatic **Renal Cell Cancer**

Resource links provided by NLM:

MedlinePlus related topics: Cancer Kidney Cancer

Genetic and Rare Diseases Information Center resources: Kidney Cancer Renal Cancer

U.S. FDA Resources

Further study details as provided by Pfizer:

Primary Outcome Measures:

- Percentage of Participants With Objective Response (OR) [Time Frame: Baseline until the date of first documented progression or discontinuation from the study due to any cause, assessed every 8 weeks up to 139 weeks] [Designated as safety issue: No]

  Percentage of participants with OR based assessment of confirmed complete response (CR) or confirmed partial response (PR) according to Response Evaluation Criteria in Solid Tumors (RECIST). Confirmed responses are those that persist on repeat imaging study at least 4 weeks after initial documentation of response. CR are defined as the disappearance of all lesions (target and/or non target). PR are those with at least 30 percent (%) decrease in the sum of the longest dimensions of the target lesions taking as a reference the baseline sum longest dimensions.

Secondary Outcome Measures:

- Time to Disease Progression (TTP) [Time Frame: Baseline until the date of first documented progression or discontinuation from the study due to any cause, assessed every 8 weeks up to 139 weeks] [Designated as safety issue: No]

Time in days from start of study treatment to first documentation of objective tumor progression or death due to cancer, whichever comes first. TTP was calculated as (first event date minus the date of first dose of study medication plus 1). Tumor progression was determined from oncologic assessment data (where data meet the criteria for progressive disease [PD]).

- Duration of Response (DR) [Time Frame: Baseline until the date of first documented progression or discontinuation from the study due to any cause, assessed every 8 weeks up to 139 weeks] [Designated as safety issue: No]

  Time in days from the first documentation of objective tumor response to objective tumor progression or death due to any cancer. Duration of tumor response was calculated as (the date of the first documentation of objective tumor progression or death due to cancer minus the date of the first CR or PR that was subsequently confirmed plus 1). DR was calculated for the subgroup of participants with a confirmed objective tumor response.

- Overall Survival (OS) [Time Frame: Baseline to death due to any cause or at least 1 year after the initial dose for the last treated participant] [Designated as safety issue: No]

  Time in days from the start of study treatment to date of death due to any cause. OS was calculated as (the death date minus the date of first dose of study medication plus 1). Death was determined from adverse event (AE) data (where outcome was death) or from follow-up contact data (where the participant current status was death). For participants who were alive, overall survival was censored at the last contact.

- Change From Baseline in European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Version 3.0 (EORTC QLQ-C30) Score [Time Frame: Baseline, Days 29, 57, 113, 169, 225, 281, 337, 393, 449, 505, 561, 617, 673, 729, 785, 841, 897, 953 and follow-up visit after last dose] [Designated as safety issue: No]

  EORTC QLQ-C30: included functional scales (physical, role, cognitive, emotional, and social), global health status, symptom scales (fatigue, pain, nausea/vomiting) and single items (dyspnea, appetite loss, insomnia, constipation/diarrhea and financial difficulties). Most questions used 4 point scale (1 'Not at all' to 4 'Very much'; 2 questions used 7-point scale (1 'very poor' to 7 'Excellent'). Scores averaged, transformed to 0-100 scale; higher score=better level of functioning or greater degree of symptoms. Change from baseline=Cycle/Day score minus baseline score.

Enrollment:	52
Study Start Date:	October 2003
Study Completion Date:	February 2007
Primary Completion Date:	February 2007 (Final data collection date for primary outcome measure)

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Histologically documented RCC with metastases.
- Failure of 1 prior cytokine-based therapy (interleukin-2 and/or interferon) due to disease progression or unacceptable treatment-related toxicity

Exclusion Criteria:

- Any prior systemic treatment for Renal Cell Carcinoma [RCC] other than 1 prior cytokine-based treatment regimen. Cytokine-based regimens containing thalidomide or an anti-angiogenesis agent are not allowed.
- Inability to take oral medication

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00076011

Locations

United States, California

Pfizer Investigational Site
San Francisco, California, **United States**, 94115

United States, Massachusetts

Pfizer Investigational Site
Boston, Massachusetts, **United States**, 02114

Pfizer Investigational Site
Boston, Massachusetts, **United States**, 02115

United States, New York

Pfizer Investigational Site
New York, New York, **United States**, 10021

United States, Ohio

Pfizer Investigational Site
Cleveland, Ohio, **United States**, 44195

United States, Pennsylvania

Pfizer Investigational Site
Philadelphia, Pennsylvania, **United States**, 19111-2497

United States, Wisconsin

Pfizer Investigational Site
Madison, Wisconsin, **United States**, 53792

France

Pfizer Investigational Site
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Germany

Pfizer Investigational Site
Hannover, Germany, 30625

Sponsors and Collaborators

Pfizer

Investigators

Study Director: Pfizer CT.gov Call Center Pfizer

More Information

Additional Information:

To obtain contact information for a study center near you, click here.

No publications provided by Pfizer

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Rixe O, Bukowski RM, Michaelson MD, Wilding G, Hudes GR, Bolte O, Motzer RJ, Bycott P, Liau KF, Freddo J, Trask PC, Kim S, Rini BI. Axitinib treatment in patients with cytokine-refractory metastatic renal-cell cancer: a phase II study. Lancet Oncol. 2007 Nov;8(11):975-84. Epub 2007 Oct 23.

Responsible Party:	Pfizer
ClinicalTrials.gov Identifier:	NCT00076011 History of Changes
Obsolete Identifiers:	NCT00077272
Other Study ID Numbers:	A4061012
Study First Received:	January 12, 2004
Results First Received:	February 25, 2012
Last Updated:	June 20, 2012
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Kidney Neoplasms	Mitosis Modulators
Kidney Diseases	Molecular Mechanisms of Pharmacological Action
Neoplasms	Pharmacologic Actions
Urologic Neoplasms	Angiogenesis Modulating Agents
Urogenital Neoplasms	Growth Substances
Neoplasms by Site	Physiological Effects of Drugs
Urologic Diseases	Growth Inhibitors
Mitogens	Antineoplastic Agents

Angiogenesis Inhibitors
Endothelial Growth Factors

Therapeutic Uses

ClinicalTrials.gov processed this record on March 27, 2014