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Trial record **1 of 3** for: axitinib | Completed | renal cell carcinoma | United States | Adult, Senior

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Study Of AG-013736 In Patients With Refractory Metastatic Renal Cell Cancer

This study has been completed.

Sponsor:
Pfizer

Information provided by (Responsible Party):
Pfizer

ClinicalTrials.gov Identifier:
NCT00282048

First received: January 23, 2006
Last updated: July 23, 2012
Last verified: July 2012
History of Changes

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Purpose

To determine the activity and response rate of **AG-013736** in patients with advanced and refractory renal cell cancer, (patients who also failed on sorafenib-based therapy).

Condition	Intervention	Phase
Kidney Neoplasms **Carcinoma**, **Renal Cell**	Drug: **AG-013736** (**axitinib**)	Phase 2

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** In Patients With Refractory Metastatic **Renal Cell Cancer**

Resource links provided by NLM:

MedlinePlus related topics: Cancer Kidney Cancer

Drug Information available for: Axitinib

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 to disease progression or discontinuation from study due to any cause, assessed every 8 weeks up to 152 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 responses. 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 of longest dimensions.

Secondary Outcome Measures:

- Progression-free Survival (PFS) [Time Frame: Baseline until the date of first documented progression or death due to any cause, assessed every 8 weeks up to 152 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 any cause. PFS 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]), or from adverse event (AE) data (where the outcome was "Death").

- Duration of Response (DR) [Time Frame: Baseline to disease progression or discontinuation from study due to any cause, assessed every 8 weeks up to 152 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 first dose for the last 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 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.

- Functional Assessment of Cancer Therapy (FACT)-Kidney Symptom Index for Disease Cancer Related Symptoms (FKSI-DRS) Score [Time Frame: Baseline (Day 1 of Cycle 1), Day 1 of all subsequent cycles up to Cycle 38 and follow up (28 days after last dose)] [Designated as safety issue: No]

  FKSI-DRS is a subset of FKSI which is a questionnaire for FACT -Kidney Symptom Index used to assess Quality of Life (QoL)/participant-reported outcomes for participants diagnosed with renal cell cancer. The FKSI contained 15 questions and the FKSI-DRS consisted of 9 questions each ranging from 0 (not at all) to 4 (very much) so that FKSI-DRS ranged between 0-36. Since the questions could be reversed coded, as appropriate, before calculating FKSI-DRS, 0 and 36 could be considered the worst and best health states based on the 9 questions comprising FKSI-DRS.

- Population Pharmacokinetics of **Axitinib** (**AG-013736**) [Time Frame: Day 1 (Pre-dose), Day 29, Day 57 and then every 8 weeks until disease progression or discontinuation from study or up to 152 weeks] [Designated as safety issue: No]

  Data for this outcome measure are not reported here because the analysis population includes participants who were not enrolled in this study. ClinicalTrials.gov is designed for reporting results from only those participants who were enrolled in the study and described in the Participant Flow and Baseline Characteristics modules.

Other Outcome Measures:

- Functional Assessment of Cancer Therapy (FACT)-Kidney Symptom Index (FKSI) Score [Time Frame: Baseline (Day 1 of Cycle 1), Day 1 of all subsequent cycles up to Cycle 38 and follow up (28 days after last dose)] [Designated as safety issue: No]

  FKSI is a questionnaire for FACT-Kidney Symptom Index used to assess QoL/participant-reported outcomes for participants diagnosed with renal cell cancer. The FKSI contained 15 questions each ranging from 0 (not at all) to 4 (very much) so that FKSI ranged between 0-60 where higher scores reflects better functioning and fewer symptoms.

- Correlation of Area Under the Concentration-time Curve at Steady State (AUCss) With Confirmed Partial Response (PR) [Time Frame: Day 1 (Pre-dose), Day 29 and then every 8 weeks until disease progression or discontinuation from study or up to 152 weeks] [Designated as safety issue: No]

  AUCss: pharmacokinetic parameter derived from plasma concentration versus time data using non-compartmental or population based analysis methods, computed as each participant's average total daily dose (accounting for dose reductions and any recorded missed doses) divided by population estimated posthoc individual apparent clearance (CL/F), i.e., AUCss = Daily Dose/(CL/F), where F refers to the oral bioavailability, and CL refers to the systemic clearance. PR: responses with at least 30% decrease in sum of longest dimensions of target lesions using baseline (pre-treatment) sum of longest dimensions as reference. Logistic regression with general linear model was applied to data of PR using AUCss; PR was correlated with AUCss as fold increase in odds of PR with increase in AUCss. Fold increase was calculated as exponent of product of logistic regression slope coefficient and unit change of AUCss.

- Relationship of Area Under the Concentration-time Curve at Steady State (AUCss) With Progression-free Survival (PFS) [Time Frame: Day 1 (Pre-dose), Day 29, and then every 8 weeks until disease progression or discontinuation from study or up to 152 weeks] [Designated as safety issue: No]

  AUCss is a pharmacokinetic parameter derived from plasma concentration versus time data using non-compartmental or population based analysis methods. PFS is median time from first dose of study treatment to the first documentation of objective tumor progression or to death due to any cause, whichever occurs first. Relationship of PFS versus AUCss was determined as median PFS in participants with high AUCss

[AUCss greater than or equal to (>=) median AUCss] or low AUCss [AUCss less than (<) median AUCss].

- Relationship of Area Under the Concentration-time Curve at Steady State (AUCss) With Overall Survival (OS) [Time Frame: Day 1 (Pre-dose), Day 29 and then every 8 weeks until disease progression or discontinuation from study or up to 152 weeks] [Designated as safety issue: No]

  AUCss is a pharmacokinetic parameter derived from plasma concentration versus time data using non-compartmental or population based analysis methods. OS is time in weeks from the start of study treatment to date of death due to any cause. Relationship of OS versus AUCss was determined as median OS in participants with high AUCss [AUCss >= median AUCss] or low AUCss [AUCss < median AUCss].

Enrollment: 62
Study Start Date: March 2006
Study Completion Date: June 2009
Primary Completion Date: February 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: **AG-013736** (**axitinib**) **AG-013736** single agent in continuous dosing until disease progression or unacceptable toxicity	Drug: **AG-013736** (**axitinib**) **AG-013736** 5 mg twice daily [bid] continuous dosing in 28 day cycles.

Eligibility

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

Criteria

Inclusion Criteria:

- RCC with metastases and nephrectomy
- failure of prior sorafenib-based therapy
- at least 1 target lesion that has not been irradiated
- adequate bone marrow, hepatic and renal function, > or equal to 18 years of age.

Exclusion Criteria:

- Gastrointestinal abnormalities
- current use or inability to avoid chronic antacid therapy
- current use or anticipated inability to avoid potent CYP3A4 inhibitors or CYP1A2 inducers
- active seizure disorder or evidence of brain metastases.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00282048

Locations

United States, Illinois

Pfizer Investigational Site
Chicago, Illinois, **United States**, 60637

United States, New York

Pfizer Investigational Site
Bronx, New York, **United States**, 10466

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Cleveland, Ohio, **United States**, 44195

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Philadelphia, Pennsylvania, **United States**, 19111-2497

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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

Responsible Party:	Pfizer
ClinicalTrials.gov Identifier:	NCT00282048 History of Changes
Other Study ID Numbers:	A4061023
Study First Received:	January 23, 2006
Results First Received:	February 25, 2012
Last Updated:	July 23, 2012
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Carcinoma	Neoplasms by Histologic Type
Carcinoma, **Renal Cell**	Adenocarcinoma
Kidney Neoplasms	Urologic Neoplasms
Kidney Diseases	Urogenital Neoplasms
Neoplasms	Neoplasms by Site
Neoplasms, Glandular and Epithelial	Urologic Diseases

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