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SU011248 Versus Interferon-Alfa As First-Line Systemic Therapy For Patients With Metastatic Renal Cell Carcinoma

This study has been completed.

Sponsor:
Pfizer

Information provided by:
Pfizer

ClinicalTrials.gov Identifier:
NCT00083889

First received: June 3, 2004
Last updated: January 19, 2010
Last verified: January 2010
History of Changes

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Purpose

The purpose of this study is to test whether **SU011248** has activity and is safe compared to interferon-alfa as first-line therapy in patients with metastatic renal cell carcinoma (RCC).

Condition	Intervention	Phase
Carcinoma, Renal Cell	Drug: Interferon-alfa Drug: **SU011248**	**Phase 3**

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

Official Title: A Phase 3, Randomized Study Of **SU011248** Versus Interferon-Alfa As First-Line Systemic Therapy For Patients With Metastatic Renal Cell Carcinoma

Resource links provided by NLM:

MedlinePlus related topics: Cancer X-Rays

Drug Information available for: Interferon Interferon Alfa-2a Sunitinib malate Sunitinib

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:

- Progression-Free Survival (PFS), Core Radiology Assessment [Time Frame: Day 28 of each 6-week cycle: duration of treatment phase] [Designated as safety issue: No]
- Progression-Free Survival (PFS), Investigator's Assessment [Time Frame: Day 28 of each 6-week cycle: duration of treatment phase] [Designated as safety issue: No]

Secondary Outcome Measures:

- Objective Response, Core Radiology Assessment [Time Frame: Day 28 of each 6-week cycle: duration of treatment phase] [Designated as safety issue: No]
- Objective Response, Investigator's Assessment [Time Frame: Day 28 of each 6-week cycle: duration of treatment phase] [Designated as safety issue: No]
- Overall Survival (OS) [Time Frame: Clinic visit or telephone contact every 2 months until death] [Designated as safety issue: No]
- Time to Tumor Progression (TTP), Core Radiology Assessment [Time Frame: Randomization to first documentation of tumor progression: duration of treatment phase] [Designated as safety issue: No]
- Time to Tumor Progression (TTP), Investigator's Assessment [Time Frame: Randomization to first documentation of tumor progression: duration of treatment phase] [Designated as safety issue: No]
- Duration of Response (DR), Core Radiology Assessement [Time Frame: Day 28 of each cycle: duraton of treatment phase] [Designated as safety issue: No]
- Duration of Response (DR), Investigator's Assessment [Time Frame: Day 28 of each cycle: duration of treatment phase] [Designated as safety issue: No]
- FACT-Kidney Symptom Index-Disease Related Symptoms (FKSI-DRS) Subscale [Time Frame: Day 1 & 28 of each cycle: duration of treatment phase] [Designated as safety issue: No]
- FACT-Kidney Symptom Index (FKSI) Subscale [Time Frame: Day 1 & 28 of each cycle: duration of treatment phase] [Designated as safety issue: No]
- Functional Assessment of Cancer Therapy-General (FACT-G) [Time Frame: Day 1 & 28 of each cycle: duration of treatment phase] [Designated as safety issue: No]
- Functional Assessment of Cancer Therapy-General (FACT-G): Physical Well Being (PWB) Subscale [Time Frame: Day 1 & 28 of each cycle: duration of treatment phase] [Designated as safety issue: No]
- Functional Assessment of Cancer Therapy-General (FACT-G): Social/Family Well Being (SWB) Subscale [Time Frame: Day 1 & 28 of each cycle: duration of treatment phase] [Designated as safety issue: No]
- Functional Assessment of Cancer Therapy-General (FACT-G): Emotional Well Being (EWB) Subscale [Time Frame: Day 1 & 28 of each cycle: duration of treatment phase] [Designated as safety issue: No]
- Functional Assessment of Cancer Therapy-General (FACT-G): Functional Well Being (FWB) Subscale [Time Frame: Day 1 & 28 of each cycle: duration of treatment phase] [Designated as safety issue: No]
- EuroQoL Five Dimension (EQ-5D) Health State Index [Time Frame: Day 1 & 28 of each cycle: duration of treatment phase] [Designated as safety issue: No]
- Euro-QoL Visual Analog Scale (EQ-VAS) [Time Frame: Day 1 & 28 of each cycle: duration of treatment phase] [Designated as safety issue: No]
- Plasma Concentrations of Soluble Proteins: Plasma VEGF-A, Plasma VEGF-C, Plasma sVEGFR-3, PLASMA IL-8, and PLASMA bFGF That May be Associated With Tumor Proliferation or Angiogenesis [Time Frame: Day 1 & Day 28, Cycle 1 to Cycle 4] [Designated as safety issue: No]
- Plasma Concentrations of Soluble Proteins: Plasma Basic Fibroblast Growth Factor (bFGF) That May be Associated With Tumor Proliferation or Angiogenesis [Time Frame: Day 1 & Day 28, Cycle 1 to Cycle 4] [Designated as safety issue: No]
- Incremental Cost Effectiveness Ratio (ICER) [Time Frame: post study measurement] [Designated as safety issue: No]
- Ctrough Concentrations of **SU011248** [Time Frame: Day 28 of Cycle 1 to Cycle 4] [Designated as safety issue: No]
- Ctrough Concentrations of Metabolite SU012662 [Time Frame: Day 28 of Cycle 1 to Cycle 4] [Designated as safety issue: No]
- Ctrough Concentrations of **SU011248** and Active Metabolite SU012662 [Time Frame: Day 28 of Cycle 1 to Cycle 4] [Designated as safety issue: No]

Enrollment:	750
Study Start Date:	August 2004
Study Completion Date:	September 2008
Primary Completion Date:	September 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: 2	Drug: Interferon-alfa 3 MIU first week, 6 MIU second week, and 9 MIU thereafter three times a week (non-consecutive days) until progression or unacceptable toxicity Other Name: Roferon
Experimental: 1	Drug: **SU011248** 50 mg orally daily for 4 weeks and 2 weeks off treatment until progression or unacceptable toxicity Other Name: **Sunitinib**, **SUTENT**

Eligibility

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

Criteria

Inclusion Criteria:

- Histologically confirmed renal cell carcinoma of clear cell histology with metastases
- Evidence of measurable disease by radiographic technique
- Eastern Cooperative Oncology Group [ECOG] performance status of 0 or 1

Exclusion Criteria:

- Prior systemic (including adjuvant or neoadjuvant) therapy of any kind for RCC
- History of or known brain metastases
- Serious acute or chronic illness or recent history of significant cardiac abnormality

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00083889

Show 124 Study Locations

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):

Cella D, Michaelson MD, Bushmakin AG, Cappelleri JC, Charbonneau C, Kim ST, Li JZ, Motzer RJ. Health-related quality of life in patients with metastatic renal cell carcinoma treated with sunitinib vs interferon-alpha in a phase III trial: final results and geographical analysis. Br J Cancer. 2010 Feb 16;102(4):658-64. doi: 10.1038/sj.bjc.6605552. Epub 2010 Jan 26.

Motzer RJ, Hutson TE, Tomczak P, Michaelson MD, Bukowski RM, Rixe O, Oudard S, Negrier S, Szczylik C, Kim ST, Chen I, Bycott PW, Baum CM, Figlin RA. Sunitinib versus interferon alfa in metastatic renal-cell carcinoma. N Engl J Med. 2007 Jan 11;356(2):115-24.

Responsible Party:	Director, Clinical Trial Disclosure Group, Pfizer Inc
ClinicalTrials.gov Identifier:	NCT00083889 History of Changes
Obsolete Identifiers:	NCT00098657
Other Study ID Numbers:	A6181034
Study First Received:	June 3, 2004
Results First Received:	September 16, 2009
Last Updated:	January 19, 2010
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Sunitinib
Carcinoma
Carcinoma, Renal Cell
Neoplasms, Glandular and Epithelial
Neoplasms by Histologic Type
Neoplasms
Adenocarcinoma
Kidney Neoplasms

Interferon Alfa-2a
Interferons
Antiviral Agents
Anti-Infective Agents
Therapeutic Uses
Pharmacologic Actions
Immunologic Factors
Physiological Effects of Drugs

Urologic Neoplasms
Urogenital Neoplasms
Neoplasms by Site
Kidney Diseases
Urologic Diseases
Interferon-alpha

Angiogenesis Inhibitors
Angiogenesis Modulating Agents
Growth Substances
Growth Inhibitors
Antineoplastic Agents

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