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# Pfizer Inc.

## Pfizer's Sutent(R) Is Granted Full Marketing Authorization for First-Line Use in Advanced Kidney Cancer in the European Union

18.01.2007 - 10:08 Uhr, Pfizer Inc.

New York (ots/PRNewswire) -

- Full marketing authorization and extension of indication to first-line treatment of advanced and/or metastatic renal cell carcinoma (MRCC)

- First multiple receptor tyrosine kinase inhibitor to be approved in the EU for first-line use in MRCC

Pfizer Inc said today that Sutent(R) (sunitinib malate) has received the European Commission's full marketing authorization for the treatment of advanced and/or metastatic renal cell carcinoma (MRCC), a type of advanced kidney cancer. It is the first multiple receptor tyrosine kinase inhibitor to be approved in the EU for first-line use in MRCC.

Sunitinib malate is an oral therapy belonging to a new class of dual-action multi-targeted drugs that attack cancer by inhibiting tumor growth and starving the tumor of blood, thereby reducing its ability to continue to divide and grow.

### Clinical Studies

The European Commission's full marketing authorization is based on data from a large phase III MRCC trial. In this multicenter international study, 750 patients received sunitinib malate or interferon-alfa (IFN alfa), the current standard of care.

Patients taking sunitinib malate had prolonged progression-free survival (PFS) in first-line treatment for MRCC.

@@start.tl@@ - Patients in the sunitinib malate arm experienced 11-month median PFS -- more than double the 5-month median PFS observed with IFN alfa.

- Sunitinib malate demonstrated a 5-fold higher objective response rate (ORR) compared with IFN alfa in first-line MRCC treatment (28% vs. 5%).
- Sunitinib malate is generally well tolerated with fewer discontinuations than IFN alfa. Fewer patients discontinued the medicine because of treatment-related adverse events (6% vs. 9%).@@end@@

"The study shows the benefits that Sutent can provide to patients," said Professor Sylvie Negrier, Deputy Director of the Centre Leon Berard, Lyon and Professor of Medicine at Lyon University. "Doubling median progression-free survival compared to the current standard treatment is a promising result, and confirms Sutent's value for this devastating disease. As a physician who regularly treats metastatic renal cell carcinoma, I am glad to be able to offer my patients an effective new treatment."

Sunitinib malate's side effects in clinical studies for the treatment of MRCC were generally mild or moderate. The most common treatment-related adverse events of any grade were fatigue; GI disorders -- diarrhea, nausea, stomatitis, dyspepsia, and vomiting; skin discoloration; dysgeusia; and anorexia.

The most severe adverse events associated with sunitinib malate vs. IFN alfa were decreased ejection fraction (2%), hand-foot syndrome (5%), thrombocytopenia (6%), neutropenia (6%), and hypertension (8%).

"Sutent has the potential to provide real improvements on the current standard of care. With this first-line European approval, these benefits can be extended to even more patients," said Dr. Joseph Feczko, Pfizer's Chief Medical Officer.

In addition to its full authorization for the treatment of MRCC in the EU, sunitinib malate is indicated for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST) after failure of imatinib mesylate treatment due to resistance or intolerance.

#### Background on Sunitinib Malate's Full Marketing Authorization for MRCC

Full approval of sunitinib malate for the treatment of MRCC includes a broadening of the initial indications that the European Commission conditionally authorized in July 2006. Based on results from two phase II studies in cytokine refractory MRCC, the Commission had granted Pfizer conditional marketing authorization in the EU. The condition was that Pfizer would provide further data on the drug's effect in terms of relevant clinical endpoints such as progression-free survival (PFS). Following evaluation of clinical data submitted by Pfizer, the European Medicines Agency (EMA) recommended removing the "conditional" status; it also recommended extending the indication to first-line treatment of advanced and/or metastatic RCC. The Commission has formally endorsed the recommendations.

In the two phase II studies in cytokine-refractory MRCC, which occurs when patients become resistant to cytokine therapy, a form of immunotherapy, the objective response rates for sunitinib malate were 38% and 36%. While median overall survival in the first of these two studies was 16.4 months, this endpoint has not yet been reached in the second study, which is ongoing, although enrollment has been completed.

For more information, please visit [www.pfizer.com](http://www.pfizer.com).

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#### Contact:

Oliver Stohlmann, +43-66-4335-0485 or +43-15-211-5337, or Vanessa

Aristide, +1-212-733-3784, both for Pfizer Inc. Company News

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