



# Single-Agent SUTENT Prolonged Progression-Free Survival across All Advanced Kidney Cancer Patient Risk Groups, Including Those with Poorest Prognoses, Data Show

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Promising Anti-Tumor Activity Also Seen in Advanced Liver Cancer

(BUSINESS WIRE)--Pfizer announced today that single-agent, oral SUTENT® (sunitinib malate) prolonged progression-free survival (PFS) across all patient risk groups, including those with the poorest prognoses for survival versus interferon-alfa (IFN- $\alpha$ ), according to new data from the Phase III trial in the first-line treatment of advanced renal cell carcinoma (RCC). These data, along with Phase II studies of SUTENT in several tumor types, including liver cancer, were presented at the 43rd American Society of Clinical Oncology (ASCO) Annual Meeting.

Advanced renal cell carcinoma, a rare but serious type of kidney cancer, is among the most treatment-resistant tumors. More than 200,000 people in the United States live with kidney cancer and approximately 12,890 people will die from this disease this year.

“SUTENT research is helping to reshape the treatment landscape in advanced kidney cancer,” said Dr. Robert Motzer, attending physician at Memorial Sloan-Kettering Cancer Center and lead investigator on the SUTENT Phase III trial in RCC. “The longer progression-free survival benefit seen across all patient subgroups studied builds on an extensive body of evidence demonstrating the efficacy and safety of SUTENT in the treatment of advanced kidney cancer.”

SUTENT is a multi-kinase inhibitor which works by inhibiting angiogenesis, one of the processes by which tumors acquire blood vessels bringing oxygen and nutrients needed for growth, and proliferation, the process by which cells multiply. The updated analysis from the randomized Phase III trial of 750 previously untreated patients with advanced RCC also demonstrated that:

The progression-free survival benefit of SUTENT vs. IFN- $\alpha$  extended across all Memorial Sloan-Kettering Cancer Center (MSKCC) prognostic risk factor groups as follows: -- Favorable risk (0 risk factors): 14.5 mo vs. 7.9 mo -- Intermediate risk (1-2 risk factors): 10.6 mo vs. 3.8 mo -- Poor risk ( $\geq 3$  risk factors): 3.7 mo vs. 1.2 mo SUTENT more than doubled PFS versus IFN- $\alpha$  (11 months vs. 5.1 months) SUTENT was associated with a significant improvement in objective response rate (ORR), a measurable response in tumor size, compared with IFN- $\alpha$ , according to both investigator assessment (46 percent vs. 12 percent) and independent central review (39 percent vs. 8 percent).

Additionally, data from an ongoing, multi-center, open-label, expanded access study of single-agent SUTENT in more than 2,000 patients with RCC were also presented today at ASCO. These data include difficult-to-treat patients such as those with brain metastases, non-clear cell kidney cancer and Eastern Cooperative Oncology Group (ECOG) status greater than or equal to two, and confirm the safety profile of SUTENT.

Results were also presented today from a pooled analysis of two single-arm Phase II trials in patients with cytokine-refractory advanced kidney cancer. Data from a study of 168 cytokine-refractory patients treated with single-agent, oral SUTENT showed an ORR of 45 percent, median PFS of 8.4 months, and median overall survival of 19.9 months. Forty-seven percent of patients were still alive at two-year follow-up.

Pfizer is committed to further exploring the effect of SUTENT in additional advanced kidney cancer populations. Currently underway are two Phase III trials studying the role of SUTENT as an adjuvant therapy, immediately after surgery, in patients at risk for cancer recurrence.

“The promising results we continue to see with SUTENT, as both a single agent and in combination with chemotherapy, further highlight the role that SUTENT may play in the treatment of numerous cancers,” said Charles Baum, MD PhD, head of oncology development at Pfizer. “Based on this evidence, Pfizer is exploring the potential utility of SUTENT through Phase III clinical trials in some of the most prevalent and difficult to treat forms of cancer, including breast, liver, colorectal and lung cancer.”

Phase II Study in Advanced Liver Cancer

As part of Pfizer's commitment to exploring new options for people living with cancer, clinical trials of sunitinib malate are also underway in other tumor types, including advanced liver cancer or hepatocellular carcinoma (HCC). Advanced liver cancer, or hepatocellular carcinoma, is one of the most common cancers globally, with approximately one million cases reported each year.

Positive data from an open-label Phase II trial evaluating 37 patients with advanced liver cancer were also presented this week at ASCO. Findings demonstrate anti-tumor activity with single-agent sunitinib malate. Decreased tumor density or tumor size was seen in 68 percent of patients treated with sunitinib malate. In addition, both the blood flow and volume (amount of blood reaching the tumor) were decreased by an average of 39 percent. Such results in this setting are encouraging and Pfizer intends to initiate Phase III studies in advanced liver cancer to fully understand the role of sunitinib malate in this setting.

#### About SUTENT® (sunitinib malate)

SUTENT is a multi-kinase inhibitor approved for the treatment of advanced renal cell carcinoma (RCC) and gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib meylate.

Women of child bearing age who are (or become) pregnant during therapy should be informed of the potential for fetal harm while on SUTENT.

Decreases in left ventricular ejection fraction (LVEF) to below the lower limit of normal (LLN) have been observed. Patients with concomitant cardiac conditions should be carefully monitored for clinical signs and symptoms of congestive heart failure.

Patients should be monitored for hypertension and treated as needed with standard antihypertensive therapy. CBCs with platelet count and serum chemistries should be performed at the beginning of each treatment cycle for patients receiving treatment with SUTENT.

The most common adverse reactions are fatigue, asthenia, diarrhea, nausea, mucositis/stomatitis, vomiting, dyspnea, abdominal pain, constipation, hypertension, rash, hand-foot syndrome, skin discoloration, altered taste, anorexia and bleeding.

For more information on SUTENT and Pfizer Oncology please visit [www.pfizer.com](http://www.pfizer.com).

DISCLOSURE NOTICE: The information contained in this release is as of June 3, 2007. Pfizer assumes no obligation to update any forward-looking statements contained in this

release as the result of new information or future events or developments.

This release contains forward-looking information about various products in development, including their potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for any such products in development as well as their decisions regarding labeling and other matters that could affect their availability or commercial potential; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 and in its reports on Form 10-Q and Form 8-K.

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