New Preliminary Phase II Data Show Anti-Tumor Activity of Single-Agent Sunitinib Malate in Advanced Gastric Cancer

Tuesday, September 25, 2007 - 10:30pm

Additional Early Data Show the Tolerability of Sunitinib in Combination with Standard of Care Chemotherapies in the Treatment of Advanced Prostate and Breast Cancers

(BUSINESS WIRE)--Preliminary results from a new Phase II study provide data on the anti-tumor activity and tolerability of sunitinib malate in patients with advanced gastric cancer. Additionally, data from phase I studies provide information on the tolerability and safety of sunitinib malate in combination with current standard of care chemotherapies in the treatment of hormone-refractory prostate cancer (HRPC) and advanced breast cancer. These data were presented this week at the 14th European Cancer Conference (ECCO 14) in Barcelona.

Gastric cancer is the fourth most common form of cancer worldwide. The development of gastric cancer has been linked to chronic infection with H. pylori, one of the most common bacterial infections worldwide with a particularly high prevalence in developing countries.

“Gastric cancer remains a leading cause of cancer death in many parts of the world and, as the cancer is often diagnosed at an advanced stage, the development of additional effective treatment options is essential,” said Yung-Jue Bang, MD, professor of Internal Medicine of the Seoul National University College of Medicine. “Though preliminary, these results are promising and support additional study of sunitinib malate in advanced gastric cancer, which typically has a poor prognosis with five-year survival around 25%.”

Phase II Study in Advanced Gastric Cancer

[Abstract # 3542; Embargoed until September 26 at 9:00 AM CET]

Preliminary findings from this phase II, open-label, multicenter study indicate that single-agent sunitinib malate showed anti-tumor activity with manageable adverse events in previously chemotherapy-treated patients with advanced gastric cancer. Patients in the trial received sunitinib malate 50mg/day, administered in six-week cycles of four weeks on treatment followed by two weeks off. The trial was Simon 2-stage design, whereby an initial 38 patients were enrolled and after initial activity was observed with sunitinib malate, a second cohort of patients was enrolled for further study. Sixteen patients remain on treatment.

Of 72 patients who received sunitinib malate, partial responses were achieved in two patients, and stable disease (SD) was achieved in 17 patients (12 with SD for >3 months and 3 for >6 months). Median progression-free survival was 11.1 weeks, with overall survival of 47.7 weeks. The most common treatment-related adverse events (AEs) were nausea and stomatitis, which were generally grade 1/2 in severity. Grade ≥3 non-hematologic treatment-related AEs included fatigue, anorexia, and hand-foot syndrome. Treatment-related grade ≥3 hematologic AEs included reduced platlets, neutrophils, and hemoglobin.

Phase I Studies in Prostate Cancer and Breast Cancer

Also presented at ECCO were results from two Phase I studies in the first-line treatment of both metastatic castrate-resistant prostate cancer, also known as hormone-refractory prostate cancer (HRPC) and advanced breast cancer, showing the tolerability and safety of sunitinib malate in combination with current standard of care chemotherapies for both cancers respectively. Preliminary evidence of activity was also observed in both studies.

A phase I, 25-patient dose-finding study found that the combination of sunitinib malate and docetaxel (dcx) + prednisone (pdn) appears to be tolerated with the optimum combination dose (OCD) being sunitinib malate 37.5 mg/day for two weeks, followed by one week off treatment, combined with dcx 75 mg/m2, given intravenously once every three weeks and pdn 5 mg administered twice daily. Docetaxel-based chemotherapy regimens are currently the standard of care for the first-line treatment of patients with HRPC. The most commonly reported treatment-related non-hematologic AEs included fatigue, dysgeusia, nausea, diarrhea and skin discoloration. Grade 3/4 non-hematologic AEs included fatigue, skin discoloration, mucosal inflammation/stomatitis and hand-foot syndrome. Grade 3/4 hematologic abnormalities included anemia, leukopenia,

neutropenia and thrombocytopenia. The study is now proceeding to its second phase in which safety and efficacy of this regimen in the first-line treatment of metastatic HRPC will be assessed. [Abstract # 4025; Embargoed until September 25 at 9:00 AM CET].

Additionally, preliminary results from a Phase I, 22-patient trial showed the tolerability and safety of sunitinib malate in combination with paclitaxel, a commonly used chemotherapy, in the first-line treatment of advanced breast cancer. No new toxicities emerged other than those seen in previous studies with sunitinib or paclitaxel. A Phase III study of this combination (sunitinib malate + paclitaxel) compared with bevacizumab plus paclitaxel in the first-line treatment of advanced breast cancer is currently underway. [Abstract #2107; Embargoed until September 26 at 2:00 PM CET].

"Some of the most pressing unmet needs in cancer treatment today are in the advanced setting," said Charles Baum, MD PhD, head of oncology development at Pfizer. "We are encouraged by the data presented this week at ECCO, as Pfizer is committed to further exploring the role sunitinib malate may play in the treatment of patients with advanced cancers, both as a single-agent and in combination."

Sunitinib Clinical Research Program

Phase III trials are underway to evaluate the role of sunitinib malate in the treatment of various solid tumors including advanced breast cancer (BC), advanced non-small cell lung cancer (NSCLC) and advanced colorectal cancer (CRC). The SUN (Studies to UNderstand Sunitinib Malate) Program is a clinical resource for professionals who are interested in learning more about sunitinib malate trials that are open for enrollment. Healthcare professionals can visit The SUN Program Web site at www.suntrials.com.

For more information about sunitinib malate trials currently open and enrolling, please visit www.suntrials.com, www.clinicaltrials.gov or call Pfizer Oncology's toll-free number at 1-866-914-6993 (U.S.) or 001-646-277-4066 (outside the U.S.).

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 mesylate. SUTENT is not approved for the treatment of gastric cancer, hormone-refractory prostate cancer or metastatic breast cancer.

Sunitinib malate works by blocking multiple molecular targets implicated in the growth, proliferation and spread of cancer. Two important sunitinib malate targets, vascular

endothelial growth factor receptor (VEGFR) and platelet-derived growth factor receptor (PDGFR) are expressed by many types of solid tumors, and are thought to play a crucial role in angiogenesis, the process by which tumors acquire blood vessels, oxygen and nutrients needed for growth. Sunitinib malate also inhibits other targets important to tumor growth, including KIT, FLT3 and RET.

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, dyspensia, 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.

DISCLOSURE NOTICE: The information contained in this release is as of September 26, 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 potential additional indications for Sutent, 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 supplemental new drug applications that may be filed for any such additional indications 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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