Sutent Significantly Improved Progression-Free Survival for Patients with Advanced Pancreatic Islet Cell Tumors

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New Data from a Phase 3 Trial Presented

(BUSINESS WIRE)--Pfizer today announced results from a randomized Phase 3 trial of Sutent (sunitinib malate) in patients with advanced pancreatic islet cell tumors, also known as pancreatic neuroendocrine tumors, which is a different type of cancer than the more common pancreatic adenocarcinoma. Study findings demonstrated that median progression-free survival (PFS) was 11.1 months in patients treated with Sutent compared to 5.5 months in patients treated with placebo. Researchers today presented these data at the 11th World Congress on Gastrointestinal Cancer in Barcelona, Spain. The independent Data Monitoring Committee (DMC) recommended halting the trial earlier this year because Sutent showed significant benefit and the study had met its primary endpoint. Full analysis of the data is ongoing.

“In this study, Sutent demonstrated an impressive improvement in progression-free survival for patients with pancreatic islet cell tumors,” said Dr. Eric Raymond, MD, PhD, Professor of Medical Oncology and Head of University Department of Medical Oncology (Service Inter Hospitalier de Cancerologie) Bichat-Beaujon, Clichy, France, and lead investigator on this sunitinib Phase 3 study. “This is encouraging news for patients, especially given that there are limited treatment options for this type of advanced cancer.”

Phase 3 Trial Results

This international, Phase 3 trial compared sunitinib to placebo in patients with progressive, well-differentiated, malignant pancreatic islet cell tumors who had progressed in the last 12 months. Patients were randomized to either the sunitinib (n=75) (37.5 mg/day, continuous daily dosing) plus best supportive care arm or the placebo plus best supportive care arm (n=79).

Results showed that median PFS was 11.1 months in patients treated with sunitinib compared to 5.5 months in patients treated in the placebo arm (Hazard ratio 0.397, $p<0.001$).

Adverse events were similar to those observed in other sunitinib studies. The most commonly reported grade 3-4 adverse events in the sunitinib arm were neutropenia (12.3 percent), hypertension (8.8 percent), abdominal pain (7 percent), diarrhea (7 percent), hypoglycemia (7 percent) and hand-foot syndrome (7 percent).

This trial was initiated based on the results of an earlier Phase 2 trial of 107 patients published in the Journal of Clinical Oncology (July 2008). A 16.7 percent overall objective response rate (RECIST) and 56.1 percent stable disease rate (SD ≥6 months) were seen in the 66 patients with advanced pancreatic islet cell tumors treated with sunitinib.

“The observation of substantial improvement in progression-free survival in Sutent-treated patients was the basis for the independent Data Monitoring Committee’s recommendation to halt accrual to the study early,” said Dr. Mace Rothenberg, Senior Vice President of Clinical Development and Medical Affairs for Pfizer’s Oncology Business Unit. “This is welcome news, as there is currently no standard of care for patients with pancreatic islet cell tumors who progress on prior therapy.”

About Pancreatic Islet Cell Tumors

In contrast to exocrine pancreatic adenocarcinoma, pancreatic islet cell tumors are rare, indolent tumors of the endocrine pancreas with an incidence of two to four people per million annually worldwide. Pancreatic islet cell tumors include insulinomas, glucagonomas and gastrinomas. Current treatment options are limited.

About Sutent(®) (sunitinib malate)

Sutent, an oral multi-kinase inhibitor, is currently approved for both advanced renal cell carcinoma (RCC) and second-line gastrointestinal stromal tumor (GIST), based on efficacy and safety data from large, randomized Phase 3 clinical trials. Sutent has played an important role in reshaping the treatment landscape for these two difficult-to-treat

cancers. To date, more than 60,000 patients globally have been treated with Sutent.

Sutent works by blocking multiple molecular targets implicated in the growth, proliferation and spread of cancer. Two important Sutent 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. Sutent also inhibits other targets important to tumor growth, including KIT, FLT3 and RET.

Sunitinib Clinical Research Program

Pfizer is pursuing a broad development program for sunitinib malate and is studying its role in the potential treatment of various solid tumors.

Healthcare professionals who are interested in learning more about sunitinib trials that are open for enrollment can visit the SUN program web site at www.suntrials.com. Patients with questions should contact their treating physician or obtain additional information through Pfizer, by calling 1-800-879-3477.

Important Sutent(®) (sunitinib malate) Safety Information

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. Complete blood counts (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 in advanced RCC and GIST clinical trials were fatigue, asthenia, diarrhea, nausea, mucositis/stomatitis, vomiting, dyspepsia, abdominal pain, constipation, hypertension, rash, hand-foot syndrome, skin discoloration, altered taste, anorexia and bleeding.

For more information on Sutent and Pfizer Oncology, including full prescribing information for Sutent (sunitinib malate), please visit www.pfizer.com.

About Pfizer Oncology

Pfizer Oncology is committed to the discovery, investigation and development of innovative treatment options for cancer patients worldwide. Our robust pipeline consists of 21 biologics and small molecules in clinical development across four scientific platforms – anti-angiogenesis, signal transduction, immuno-oncology, and cytotoxic potentiators. Pfizer Oncology has over 200 clinical trials including robust Phase 3 clinical trial programs in renal cell carcinoma, prostate cancer, non-small cell lung cancer, advanced breast cancer, colorectal cancer, and hepatocellular carcinoma.

By working collaboratively with academic institutions, researchers, governments and licensing partners, Pfizer Oncology strives to transform treatment by targeting the right drug for the right patient at the right time.

For more information please visit www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of June 25, 2009. 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 certain 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 drug applications that may be filed for additional indications for Sutent as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of any such additional indications; and competitive developments.

A further list and description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and in its reports on Form 10-Q and Form 8-K.

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