

Pfizer Discontinues One Sunitinib Phase 3 Trial in Advanced Breast Cancer; Other Advanced Breast Cancer Trials Continue

Wednesday, April 01, 2009 - 10:59pm

[\(BUSINESS WIRE\)](#)--Pfizer Inc today announced the discontinuation of one of its Phase 3 studies based on statistical assessment for futility: the SUN 1107 Phase 3 study of Sutent[®] (sunitinib malate) in advanced breast cancer. SUN 1107 evaluated single-agent sunitinib versus single-agent capecitabine for the treatment of a broad range of patients with advanced breast cancer after failure of standard treatment. An independent Data Monitoring Committee (DMC) found that even if the trial had been allowed to continue, treatment with single-agent sunitinib would be unable to demonstrate a statistically significant improvement in the primary endpoint of progression-free survival (PFS) compared to single-agent capecitabine in the study population. Data from this trial are currently being analyzed.

“We are disappointed with these results given the previous findings that suggested sunitinib may provide benefit for patients with this difficult-to-treat cancer,” said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs for Pfizer’s Oncology Business Unit. “In ongoing studies, we remain committed to evaluating sunitinib in advanced breast cancer and are continuing to study sunitinib in different populations and with different regimens.”

Pfizer has notified clinical trial investigators involved in the study and regulatory agencies of these findings. The Company encourages investigators to determine the best course of action for their individual patients.

The company is continuing to evaluate sunitinib as a single-agent and in combination with standard-of-care chemotherapy in specific patient populations with advanced breast cancer through three additional Phase 3 and two Phase 2 trials.

Sunitinib is currently approved for both gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate, and advanced / metastatic renal cell carcinoma (RCC) based on efficacy and safety data from large, randomized Phase 3 clinical trials. Sunitinib has played an important role in reshaping the treatment landscape for these two difficult-to-treat cancers. To date, more than 58,000 patients globally have been treated with sunitinib in the clinical setting and in clinical trials.

Sunitinib Clinical Research Program

Pfizer Oncology is committed to helping to improve the lives of breast cancer patients and is dedicated to further developing agents for the treatment of patients in the advanced breast cancer setting – a patient population with significant unmet medical needs.

Pfizer is also continuing to study the role of sunitinib in the treatment of various other solid tumors including advanced non-small cell lung cancer, advanced colorectal cancer, advanced hepatocellular carcinoma and advanced hormone-refractory prostate cancer, in Phase 3 trials.

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.

About Advanced Breast Cancer

Breast cancer is the most common cancer and the leading cause of cancer-related death among women globally. Compared to early stage breast cancer, effective therapy for advanced breast cancer, which includes inoperable locally advanced and metastatic disease, remains a clinical challenge in the oncology community. Additional treatment options are desperately needed to address this continuing unmet medical need.

About Sutent® (sunitinib malate)

Sutent is an oral multi-kinase inhibitor approved for the treatment of GIST after disease progression on or intolerance to imatinib mesylate and advanced / metastatic RCC.

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.

Important Sutent® (sunitinib malate) Safety Information

Women of childbearing 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 GIST and RCC 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.

DISCLOSURE NOTICE: The information contained in this release is as of April 2. 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.

Pfizer IncMedia:Jack Cox, 212-733-5017ORInvestors:Jennifer Davis, 212-733-0717