Pfizer Discontinues SUN 1094 Trial of Sunitinib plus Paclitaxel in Advanced Breast Cancer

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Two Other Phase 3 Advanced Breast Cancer Trials of Sunitinib Continue

(BUSINESS WIRE)--Pfizer Inc today announced the discontinuation of the SUN 1094 Phase 3 study that evaluated SUTENT® (sunitinib malate) plus paclitaxel versus bevacizumab plus paclitaxel for the first line treatment of patients with advanced breast cancer. The independent Data Monitoring Committee (DMC) found that treatment with sunitinib in combination with paclitaxel would be unable to meet the primary endpoint of superior progression-free survival (PFS) compared to the combination of bevacizumab and paclitaxel. No new safety issues were identified.

“While we are disappointed that this trial did not meet its primary endpoint, we are continuing to study sunitinib in different breast cancer populations and with different regimens,” said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs for Pfizer’s Oncology Business Unit. ”Pfizer remains committed to evaluating sunitinib in advanced breast cancer through its two other Phase 3 clinical trials investigating the effectiveness of Sutent in combination with standard of care chemotherapies.”

One Phase 3 trial (SUN 1064) is a comparison of SUTENT plus docetaxel vs. docetaxel for the first line treatment of patients with advanced breast cancer, and the second (SUN 1099) is a Phase 3 trial of SUTENT plus capecitabine vs. capecitabine for the second line treatment of patients with advanced breast cancer. These trials are ongoing with an analysis expected by the end of the year or early next year.

Pfizer has notified clinical trial investigators involved in the study and regulatory agencies of these findings.

These results do not affect the approved indications with sunitinib as monotherapy. 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 approximately 58,000 patients globally have been treated with sunitinib.

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 potential 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 June 1, 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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