Two Phase 3 Trials Of Sunitinib With Commonly Used Chemotherapies In Advanced Breast Cancer Did Not Meet The Primary Endpoint

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Detailed Results to be Presented at Future Medical Meeting

(BUSINESS WIRE)--Pfizer Inc. announced today that two Phase 3 studies of Sutent® (sunitinib malate) in advanced breast cancer did not meet their primary endpoints. The SUN 1064 Phase 3 study of sunitinib in combination with docetaxel for the first-line treatment of patients with advanced HER-2 negative breast cancer did not show a statistically significant improvement in progression-free survival compared with docetaxel alone. In addition, the SUN 1099 Phase 3 study of sunitinib plus capecitabine, in previously-treated advanced breast cancer patients, did not show a statistically significant improvement in progression-free survival compared with capecitabine alone.

“Sunitinib has been thoroughly evaluated in advanced HER-2 negative breast cancer, and while we are disappointed in the results, these trials have helped us define the limits and opportunities for the compound and better understand the complex biology of this disease,” said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs for Pfizer’s Oncology Business Unit. “Pfizer Oncology is committed to the rigorous evaluation of investigational therapies in breast cancer, which despite recent advancements, continues to claim far too many lives each year.”

There were more adverse events, including serious adverse events, in the investigational arm than in the comparator arm of each study. A continuing analysis of efficacy and safety data will be completed and presented at a medical meeting in the near future.

Sutent 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. Sutent has played a significant role in advancing the treatment landscape and remains standard of care in its approved indications. To date, more than 82,000 patients globally have been treated with sunitinib in the clinical setting and in trials across multiple tumors.

Pfizer remains committed to the development program for sunitinib and is continuing to study its potential role in the treatment of other solid tumors including advanced non-small cell lung cancer, advanced castration-resistant prostate cancer, advanced hepatocellular carcinoma, and as adjuvant therapy for renal cell carcinoma, in Phase 3 trials.

Pfizer Oncology is dedicated to further understanding and developing agents to better match specific patients with treatments and increase benefits from selected therapies.

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.

About Pfizer Oncology

Pfizer Oncology is committed to the discovery, investigation and development of innovative treatment options to improve the outlook for cancer patients worldwide. Our strong pipeline, one of the most robust in the industry, is studied with precise focus on identifying and translating the best scientific breakthroughs into clinical application for patients across a wide range of cancers, including breast, lung, prostate, sarcoma, melanoma, and various hematologic cancers. Pfizer Oncology has biologics and small molecules in clinical development and more than 200 clinical trials underway.

By working collaboratively with academic institutions, individual researchers, cooperative research groups, governments, and licensing partners, Pfizer Oncology strives to cure or control cancer with breakthrough medicines, to deliver the right drug for each patient at the right time.

For more information please visit www.Pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of March 11, 2010. Pfizer assumes no obligation to update 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, 2009 and in its reports on Form 10-Q and Form 8-K.

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