Pfizer Discontinues Phase 3 Trial of Sutent® in Metastatic Colorectal Cancer

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(BUSINESS WIRE)--Pfizer Inc announced today the discontinuation of the SUN 1122 Phase 3 trial that evaluated Sutent® (sunitinib malate) plus FOLFIRI (irinotecan plus infusional 5-fluorouracil and leucovorin) versus FOLFIRI alone for the first-line treatment of metastatic colorectal cancer (CRC). The independent Data Monitoring Committee (DMC) found that the addition of sunitinib to the chemotherapy regimen FOLFIRI would be unable to demonstrate a statistically significant improvement in the primary endpoint of progression-free survival (PFS) compared to FOLFIRI alone, in this study. No new safety issues were identified.

“We are disappointed with this result, but trial successes and failures are an integral part of cancer drug development and contribute to a growing body of knowledge on improving patient care,” said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs for Pfizer’s Oncology Business Unit. “Pfizer remains committed to developing new agents for colorectal and other GI cancers with ongoing clinical studies evaluating other agents in its pipeline. Investigators will be consulted about the status of sunitinib colorectal studies other than the SUN 1122 trial. Pfizer also continues to study sunitinib in late-stage trials as a potential treatment for various other types of cancer.”

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, where it has played a significant role in advancing the care of patients. 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. To date, over 50,000 patients have been treated globally.

Sunitinib Clinical Research Program

Pfizer Oncology is committed to exploring and delivering innovative therapies to patients with cancer, and is continuing to study the potential role of sunitinib in the treatment of various solid tumors including advanced non-small cell lung cancer, advanced breast 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 Colorectal Cancer (CRC)

About 630,000 deaths from CRC were estimated to occur in 2007 worldwide, accounting for eight percent of all cancer deaths. Five-year survival rates for patients with metastatic disease, cancer that has spread to distant parts of the body, such as the liver, are much lower, at 11 percent.

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 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 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, 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.

Pfizer Inc: Working together for a healthier world™

Founded in 1849, Pfizer is the world's premier biopharmaceutical company taking new approaches to better health. We discover, develop, manufacture and deliver quality, safe and effective prescription medicines to treat and help prevent disease for both people and animals. We also partner with healthcare providers, governments and local communities around the world to expand access to our medicines and to provide better quality health care and health system support. At Pfizer, more than 80,000 colleagues in more than 90 countries work every day to help people stay happier and healthier longer and to reduce the human and economic burden of disease worldwide.

DISCLOSURE NOTICE: The information contained in this release is as of June 30, 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 product candidates and 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 drug applications and supplemental drug applications that may be filed for such product candidates and such additional indications for Sutent as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such product candidates and such additional indications for Sutent; 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, 2008 and in its reports on Form 10-Q and Form 8-K.

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