Pfizer Oncology Initiates Global Phase III Trial to Evaluate Sunitinib Malate Combined with Erlotinib in Advanced Non-Small Cell Lung Cancer

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Phase II Preliminary Data for Sunitinib Presented at the 12th World Conference on Lung Cancer

(BUSINESS WIRE)--Pfizer announced today the initiation of a large, global Phase III clinical trial to evaluate the efficacy and safety of sunitinib malate, in combination with erlotinib, in previously treated patients with advanced non-small cell lung cancer (NSCLC). In addition, preliminary results from a Phase II study, presented this week at the International Association for the Study of Lung Cancer (IASLC) World Conference in Seoul, Korea, provided information on the safety and tolerability of sunitinib in combination with erlotinib in patients with advanced NSCLC.

Lung cancer is the leading cause of cancer in men and women around the globe. Nearly 60 percent of NSCLC patients are diagnosed late with Stage IIIB/IV advanced disease and most have evidence of distant metastases at the time of diagnosis.

“This Phase III trial is investigating the potential benefit of the multi-kinase inhibitor sunitinib, combined with an EGFR inhibitor, erlotinib, in treatment of advanced lung cancer,” said Dr. Keunchil Park, MD, PhD, Samsung Medical Center, Sungkyunkwan University School of Medicine. “Survival rates in lung cancer continue to be low in comparison with other cancers despite currently available treatments. It is our hope that

this approach will provide an option for patients fighting advanced lung cancer.”

Sunitinib Phase III Trial in Advanced NSCLC (SUN 1087)

Pfizer Oncology has initiated a global Phase III study to evaluate the potential role of sunitinib in previously treated patients with advanced NSCLC. This large, randomized, double-blind trial of 956 patients is designed to compare the overall survival of patients taking sunitinib combined with erlotinib (a targeted therapy used to treat NSCLC) with those taking erlotinib plus placebo. Secondary endpoints of the study include progression-free survival, objective response rate, 1-year survival, duration of response, adverse events and patient-reported outcomes.

Phase II Studies in Advanced NSCLC (SUN 1058)

Preliminary results of a lead-in safety cohort of sunitinib combined with erlotinib in previously treated advanced NSCLC, were presented at the IASLC meeting this week. The primary objective of the lead-in cohort was assessment of the safety and tolerability of sunitinib combined with erlotinib. Secondary endpoints included an assessment of the pharmacokinetics and anti-tumor activity.

The early results indicated that adverse events (AEs) from 12 patients receiving sunitinib 37.5 mg/day given continuously with erlotinib 150 mg/day were mild to moderate in severity (grade 1 or 2) at the tested doses and schedule. The most frequent AEs (n=7) were diarrhea and fatigue. Other AEs (Grade 3) included acne, nausea, anemia, dehydration, gastroesophageal reflux disease, paronychial inflammation, purities, rash and vomiting(each n=1).

As of August 2007, two patients had experienced a partial response (PR): One patient demonstrated a PR after two cycles of therapy, which was maintained for >3 months, and the second patient has a documented durable PR and continues on the study. In addition, stable disease for ≥16 weeks has been observed in two patients. Anti-tumor response was assessed according to RECIST criteria. The tolerability and activity observed in this lead-in cohort, supports the randomized Phase II portion of this study, which is now enrolling to further evaluate this combination in NSCLC.

Also presented at IASLC was a poster on results from the extension of a Phase II trial demonstrating the activity and safety of continuous daily dosing of single-agent sunitinib 37.5 mg/day in 47 previously treated patients with advanced, recurrent NSCLC, who had received one to two prior chemotherapy regimens. These data were presented earlier this year at the American Society of Clinical Oncology (ASCO) annual meeting.

“We are encouraged by the early data we are seeing for sunitinib in NSCLC” said Charles Baum, MD PhD, head of oncology development at Pfizer. “Pfizer is committed to further exploring the potential role of sunitinib in advanced NSCLC through the initiation of SUN 1087, a global, Phase III study.”

Sunitinib Clinical Research Program

Phase III trials are underway to evaluate the role of sunitinib malate in the treatment of various solid tumors including advanced breast cancer (BC), advanced non-small cell lung cancer (NSCLC) and advanced colorectal cancer (CRC). The SUN (Studies to UNderstand Sunitinib Malate) Program is a clinical resource for professionals who are interested in learning more about sunitinib malate trials that are open for enrollment. Healthcare professionals can visit The SUN Program Web site at www.suntrials.com.

For more information about sunitinib malate trials currently open and enrolling, please visit, www.suntrials.com, www.clinicaltrials.gov or call Pfizer Oncology’s toll-free number at 1-866-914-6993 (U.S.) or 001-646-277-4066 (outside the U.S.).

About SUTENT® (sunitinib malate)

SUTENT is a multi-kinase inhibitor approved for the treatment of advanced renal cell carcinoma (RCC) and gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate. SUTENT is not approved for the treatment of NSCLC, BC or CRC.

Sunitinib malate works by blocking multiple molecular targets implicated in the growth, proliferation and spread of cancer. Two important sunitinib malate 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.

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. CBCs with platelet count and serum chemistries should be performed at the beginning of each treatment cycle for patients receiving treatment with SUTENT.

In an ongoing clinical trial of patients with metastatic non-small cell lung cancer (NSCLC), fatal pulmonary hemorrhage occurred in two patients, both with squamous cell histology.

The most common adverse reactions are fatigue, asthenia, diarrhea, nausea, mucositis/stomatitis, vomiting, dyspensia, abdominal pain, constipation, hypertension, rash, hand-foot syndrome, skin discoloration, altered taste, anorexia and bleeding.

For more information on SUTENT and Pfizer Oncology please visit www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of September 5, 2007. 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 a potential additional indication for sunitnib malate, including its 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 that may be filed for this additional indication as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; 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, 2006 and in its reports on Form 10-Q and Form 8-K.

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