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Pfizer Initiates Phase III Trial to Study Sunitinib Malate in Patients with Metastatic Colorectal Cancer

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New Phase I Data Evaluating Sunitinib Malate in Patients with Metastatic Colorectal Cancer Presented at the World Congress on Gastrointestinal Cancer

(BUSINESS WIRE)--Pfizer announced today the initiation of a Phase III clinical trial to evaluate the safety and efficacy of sunitinib malate, in combination with a standard chemotherapy regimen, in patients with metastatic colorectal cancer (mCRC) - cancer originating in the colon that has spread to other parts of the body. In addition, new data from a Phase I study being presented this week at the World Congress on Gastrointestinal Cancer (WCGC) in Barcelona showed that sunitinib malate is active and generally well-tolerated in combination with a standard chemotherapy regimen, FOLFIRI, in previously untreated patients with mCRC. These data support further evaluation of sunitinib malate in mCRC in a Phase III program.

“We are encouraged by these data, which add to a growing body of research demonstrating the activity and tolerability of sunitinib malate in numerous cancers,” said Charles Baum, MD PhD, head of oncology development at Pfizer. “Based on these early findings presented this week, Pfizer is committed to continued exploration of sunitinib malate in the treatment of advanced colorectal cancer through a global Phase III program.”

Sunitinib Malate Phase III Trial in Colorectal Cancer

A multi-national Phase III study is currently open and enrolling in Europe, Canada, Asia and South America and will include more than 700 patients to evaluate the safety and efficacy of sunitinib malate combined with FOLFIRI, a standard chemotherapy regimen used in mCRC comprised of fluorouracil (5-FU), folinic acid (leucovorin), and irinotecan, compared with FOLFIRI plus placebo, in the first-line treatment of patients with mCRC.

Sunitinib malate is a multi-kinase inhibitor which works by inhibiting angiogenesis, the process by which tumors acquire blood vessels bringing oxygen and nutrients needed for growth, and proliferation, the process by which cells multiply.

Phase I Study in Metastatic Colorectal Cancer

New data presented this week from an ongoing, open-label Phase I trial of 16 previously untreated mCRC patients randomized to three distinct dosing regimens, determined the maximum tolerated dose (MTD) for sunitinib malate of four weeks on treatment followed by two weeks off (4/2) in combination with FOLFIRI was 37.5 mg/day. This regimen appeared to be active and generally well-tolerated in patients who have received no prior treatment for metastatic disease. Of the 10 patients who received this dosing regimen, four patients experienced partial response to date and stable disease has been observed in six patients. Treatment emergent

grade ?3 adverse events for patients on the sunitinib malate 37.5 mg/day 4/2 regimen were one case of respiratory tract infection and two cases of neutropenia without fever.

“Despite progress in recent years, colorectal cancer remains a hard-to-treat cancer for which new options are sorely needed,” said Alfredo Carrato MD, PhD, Elche University Hospital and lead investigator on the sunitinib malate multi-national Phase III trial in mCRC. “These data support further research of sunitinib malate in metastatic colorectal cancer, in an effort to potentially expand the range of therapies available to physicians and patients.”

For more information about sunitinib malate trials currently open and enrolling, please visit www.ClinicalTrials.gov or www.suntrials.com or call Pfizer Oncology’s toll-free number at 001-646-277-4066.

DISCLOSURE NOTICE: The information contained in this release is as of June 28, 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 that involves substantial risks and uncertainties about a potential additional indication for sunitinib malate, including its potential benefits. 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 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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