SUTENT® Receives European Approval for a New Indication in Progressive Pancreatic Neuroendocrine Tumors (NET)

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First Targeted Therapy Approved for the Treatment of Pancreatic NET in Europe

"As the first anti-VEGF therapy to show a substantial clinical benefit in treating progressive pancreatic NET, SUTENT represents a novel therapeutic approach for this difficult-to–treat disease."

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that the European Commission has approved SUTENT® (sunitinib malate) for the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumors (NET) with disease progression in adults. Experience with SUTENT as initial treatment is limited in this disease. Pancreatic NET is a rare cancer reported in two to four people per million annually worldwide.(1,2) Sutent is the first treatment to be approved for patients with pancreatic NET in twenty-five years.(3)

The approval is based on results from a randomized, Phase 3 trial that demonstrated SUTENT more than doubled the time period that patients were free from disease progression or death. The progression-free survival (PFS) for SUTENT was 11.4 months vs. 5.5 months for placebo (p=0.0001) in 171 patients. Additionally, while the overall survival data were not mature at the time of analysis, the overall survival favored the SUTENT arm compared with placebo (9 vs. 21 deaths) (HR 0.409, p=0.0204).(4)

"This approval represents a significant milestone in the management of pancreatic NET," said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs, Pfizer Oncology Business Unit. "SUTENT has been a standard of care for patients with advanced/metastatic renal cell carcinoma (RCC) and imatinib-refractory gastrointestinal stromal tumor (GIST) for several years, and we are proud that it is now a treatment option for patients in Europe with progressive pancreatic NET."

Although rare, the reported incidence of pancreatic NET appears to be rising,(2,5) accounting for approximately nine percent of neuroendocrine tumors.(5) Current treatment options have limited therapeutic benefit and the prognosis is poor for patients with advanced pancreatic NET.(6)

"As the first anti-VEGF therapy to show a substantial clinical benefit in treating progressive pancreatic NET, SUTENT represents a novel therapeutic approach for this difficult-to–treat disease." said Dr. Eric Raymond, principal investigator of the pivotal Phase 3 study that led to the approval of Sutent for pancreatic NET in Europe. "Physicians in Europe will now be able to use a therapy with proven efficacy to treat this disease." Dr. Raymond is professor of medical oncology and head of University Department of Medical Oncology (Service Inter Hospitalier de Cancerologie) Bichat-Beaujon, Clichy, France.

SUTENT is also approved for the treatment of unresectable well-differentiated advanced and/or metastatic pancreatic neuroendocrine carcinoma in the Philippines, Switzerland, Colombia and Korea. In addition, it is under regulatory review for this indication in several other countries.

About Pancreatic Neuroendocrine Tumors

Tumors of the neuroendocrine system are typically classified into two distinct categories: carcinoids or pancreatic neuroendocrine tumors. Pancreatic neuroendocrine tumors, also known as pancreatic islet cell tumors, form in the endocrine (hormone-producing) tissues of the pancreas.(7) Subtypes include insulinomas, glucagonomas and gastrinomas. Pancreatic neuroendocrine tumors are different from pancreatic adenocarcinoma, which account for about 95 percent of all pancreatic cancers.(7)

About SUTENT(®) (sunitinib malate)

SUTENT is an oral multi-kinase inhibitor approved for the treatment of advanced/metastatic renal cell carcinoma (RCC) and unresectable and/or metastatic malignant gastrointestinal stromal tumor (GIST) after failure of imatinib mesilate

treatment due to resistance or intolerance. In Europe, SUTENT is also indicated for the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumors with disease progression in adults. Experience with SUTENT as first-line treatment is limited

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

Hepatotoxicity has been observed in clinical trials and post-marketing experience. Cases of hepatic failure, some with a fatal outcome, were observed in <1% of solid tumor patients treated with SUTENT. It is recommended to monitor liver function tests before initiation of treatment, during each cycle of treatment, and as clinically indicated. If signs or symptoms of hepatic failure are present, sunitinib should be discontinued and appropriate supportive care should be provided.

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 GIST, RCC and pancreatic NET clinical trials were diarrhea, fatigue, asthenia, nausea, mucositis/stomatitis, anorexia, vomiting, neutropenia, hypertension, dyspepsia, abdominal pain, constipation, rash, hand-foot syndrome, skin discoloration, hair color changes, altered taste 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. Pfizer Oncology has biologics and small molecules in clinical development and more than 100 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 December 2, 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 that involves substantial risks and uncertainties about the pancreatic NET indication for Sutent in countries in which that indication is under regulatory review. Such risks and uncertainties include, among other things, decisions by regulatory authorities in those countries regarding whether and when to approve supplemental drug applications that have been filed for such 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, 2009 and in its reports on Form 10-Q and Form 8-K.

(1) Ramage JK, Davies AHG, Ardill et al. Guidelines for the management of gastroenteropancreatic neuroendocrine (including carcinoid) tumors. Gut. 2005;54:iv1–16. (2) Halfdanarson TR, Rabe KG, Rubin J et al. Pancreatic neuroendocrine tumors (PNETs): incidence, prognosis and recent trend toward improved survival. Ann Oncol. 2008;19:1727–33
(3) U.S. Food and Drug Administration. Drugs@FDA: Zanosar.

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(4) Niccoli, P., Raoul, J., Bang, Y., et al. Updated safety and efficacy results of the phase

III trial of sunitinib (SU) vs placebo (PBO) for treatment of pancreatic neuroendocrine tumors (NET). ASCO 2010. (5) Yao JC, Hassan M, Phan A, Dagohoy C, Leary C, Mares JE, Abdalla EK, Fleming JB, Vauthey JN, Rashid A, Evans DB. One hundred years after "carcinoid": epidemiology of and prognostic factors for neuroendocrine tumors in 35,825 cases in the United States. J Clin Oncol. Jun 20 2008;26(18):3063-3072. (6) Yao JC, Eisner MP, Leary C, et al. Population-based study of islet cell carcinoma. Ann Surg Oncol. 2007;14(12):3492-3500.

(7) National Cancer Institute. Islet Cell Tumors (Endocrine Pancreas) Treatment – Patient Version. Available at: http://www.cancer.gov/cancertopics/pdq/treatment/isletcell/patient/allpages. Accessed January 5, 2010.

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