Pfizer Announces Positive Phase 3 Trial Results for Axitinib in Patients With Previously-Treated Metastatic Renal Cell Carcinoma (mRCC)

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Detailed Study Results Expected to be Presented at an Upcoming Medical Meeting

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that the Phase 3 AXIS 1032 trial (A4061032), studying the investigational compound axitinib in previously treated patients with metastatic renal cell carcinoma (mRCC), has met its primary endpoint, demonstrating that axitinib significantly extended progression-free survival (PFS) when compared to sorafenib, in the study population. Consistent with previous analyses, axitinib demonstrated a generally manageable safety profile in this study.

"It is gratifying that in this trial axitinib provided significant benefit to patients with advanced RCC whose disease had progressed after 1st-line therapy," said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs for Pfizer's Oncology Business Unit. "These results provide insight into the potential value of axitinib as part of a sequential treatment approach in patients with advanced RCC. We will work with health authorities to determine possible filing options for axitinib for use in patients with advanced RCC."

Each year, approximately 210,000 people worldwide are diagnosed with kidney cancer and nearly 102,000 people are expected to die from the disease. Within the last five years, great advances have been made in the treatment of patients with advanced RCC, the most prevalent form of kidney cancer. However, five-year survival rates for patients with advanced RCC remain low, at around 20 percent.

About the Investigational Agent Axitinib

Axitinib is an oral and selective inhibitor of vascular endothelial growth factor (VEGF) receptors 1, 2 and 3. VEGF receptors 1, 2 and 3 appear to have roles in tumor growth, vascular angiogenesis and metastatic progression of cancer (the spread of tumors). Axitinib is an investigational agent and has not been approved by regulatory agencies.

Axitinib Clinical Research Program

Pfizer continues to investigate the potential role of axitinib across several tumor types, including a Phase 3 study of treatment-naive and previously treated patients with mRCC.

Healthcare professionals who are interested in learning more about Pfizer Oncology clinical trials that are open for enrollment can visit www.PfizerOncology.com/clinicaltrials. Patients with questions should contact their treating physician.

Advancing the Science of Kidney Cancer

As a leader in the treatment of advanced RCC, Pfizer Oncology is dedicated to extending survival in as many patients as possible by offering existing treatments and investigating new agents in different populations and stages of disease. Pfizer's RCC portfolio offers two approved therapies for the treatment of people with advanced RCC, Sutent® (sunitinib malate) and Torisel® (temsirolimus). By working collaboratively with academic institutions, individual researchers, cooperative research groups, governments, licensing partners and people affected, we are committed to advancing the science of RCC through research into established and novel compounds, as well as the exploration of biomarkers to better personalize therapy.

About Sutent® (sunitinib malate)

Sutent is an oral multi-kinase inhibitor approved for the treatment of advanced RCC and for the treatment of GIST after disease progression on or intolerance to imatinib mesylate.

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. This hepatotoxicity may be severe, and deaths have been reported. It is recommended to monitor liver function tests before initiation of treatment, during each cycle of treatment, and as clinically indicated. Sutent should be interrupted for Grade 3 or 4 drug-related hepatic adverse events and discontinued if there is no resolution. Sutent should not be restarted if patients subsequently experience severe changes in liver function tests or have other signs and symptoms of liver failure.

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 and RCC clinical trials were diarrhea, fatigue, asthenia, nausea, mucositis/stomatitis, anorexia, vomiting, hypertension, dyspepsia, abdominal pain, constipation, rash, hand-foot syndrome, skin discoloration, altered taste and bleeding.

For more information on Sutent including full prescribing information please visit www.pfizer.com.

About Torisel® (temsirolimus)

Torisel is the only intravenous mammalian target of rapamycin (mTOR) inhibitor approved for the treatment of advanced renal cell carcinoma (RCC).

Based on preclinical studies, Torisel inhibits the activity of mTOR, an intracellular protein implicated in multiple growth-related cellular functions including proliferation, growth and survival. The inhibition of mTOR also reduces levels of certain growth factors, such as vascular endothelial growth factor (VEGF), which are overexpressed in solid tumors like kidney cancer and are thought to play a crucial role in angiogenesis, the process by which tumors acquire blood vessels, nutrients and oxygen needed for growth.

Important Torisel® (temsirolimus) Safety Information

Torisel is contraindicated in patients with bilirubin >1.5 times the upper limit of normal (ULN). If Torisel must be given to patients with mild hepatic impairment, it should be used with caution and at a reduced dose.

Torisel has been associated with serious and sometimes fatal side effects including: hypersensitivity reactions, hyperglycemia/glucose intolerance, infections, interstitial lung disease, hyperlipidemia, bowel perforation, renal failure, wound healing complications, and intracerebral hemorrhage.

Live vaccines and close contact with those who received live vaccines should be avoided. Women of childbearing potential should be advised of the potential hazard to the fetus and avoid becoming pregnant.

The most common adverse reactions (incidence greater than or equal to 30%) are rash, asthenia, mucositis, nausea, edema, and anorexia. The most common laboratory abnormalities (incidence greater than or equal to 30%) are anemia, hyperglycemia, hyperlipidemia, hypertriglyceridemia, elevated alkaline phosphatase, elevated serum creatinine, lymphopenia, hypophosphatemia, thrombocytopenia, elevated AST, and leucopenia.

Strong inducers of CYP3A4/5 and inhibitors of CYP3A4 may affect concentrations of the primary metabolite of Torisel. If alternatives cannot be used, dose modifications of Torisel are recommended.

For more information on Torisel, including full prescribing information 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 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.

Pfizer Inc: Working Together for a Healthier World™

At Pfizer (NYSE: PFE), we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of November 19, 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 potential indications for axitinib, 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 that may be filed for such indications as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such indications; 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.

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