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Pfizer Presents New Phase 3 Data Showing Axitinib Significantly Extended Progression-Free Survival Compared With Sorafenib In Patients With Previously-Treated Advanced Renal Cell Carcinoma

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First Potential Treatment to Demonstrate Significant PFS Improvement vs. a Targeted Agent in a Phase 3 Trial in Advanced RCC

"The clinically meaningful improvement in PFS seen with axitinib is even more encouraging as it was accompanied by generally manageable tolerability, an important consideration for these patients."

(BUSINESS WIRE)--Pfizer Inc. today announced data from the pivotal Phase 3 AXIS 1032 trial, showing that in patients with previously treated advanced renal cell carcinoma (RCC), axitinib significantly extended progression-free survival (PFS) [HR=0.665, 95% CI; P<0.0001], with a median PFS of 6.7 months (95%CI, 6.3-8.6), compared with 4.7 months (4.6-5.6) for those treated with sorafenib, a standard of care for this patient population. PFS was significantly longer in axitinib-treated patients compared to those treated with sorafenib, regardless of prior therapy with Sutent® (sunitinib malate) or cytokines. These data will be presented on June 6 th at the 47th Annual American Society of Clinical Oncology (ASCO) meeting in Chicago from June 3-7, 2011.

“We are very pleased that this Phase 3 trial met its primary endpoint and demonstrated that axitinib could prolong median PFS to more than six months in patients with previously treated advanced RCC. It is notable that in the subset of patients previously treated with cytokines, axitinib extended median PFS to greater than a year," said Dr. Mace Rothenberg, senior vice president of clinical development and medical affairs for Pfizer’s Oncology Business Unit. “We hope that axitinib will be approved as an additional therapeutic option for patients with advanced RCC, alongside Pfizer’s two medications approved in this disease, Sutent and Torisel.”

Pfizer is working with global health authorities on filing submissions for axitinib in RCC.

About the AXIS 1032 Data To Be Presented at ASCO

In this global study, including centers in the U.S., E.U. and Japan, 723 patients with clear-cell advanced RCC who had progressed following prior therapy with regimens containing sunitinib (54 percent), cytokines (35 percent), bevacizumab (8 percent) or temsirolimus (3 percent) were enrolled. Participants received either axitinib at a starting dose of 5mg twice daily or sorafenib 400mg twice daily (N=361 and 362). PFS was statistically significantly longer in axitinib-treated patients in both the prior cytokine-treated subgroup (12.1 vs 6.5 months; P<0.0001) and the prior sunitinib-treated subgroup (4.8 vs 3.4 months; P=0.0107), with a 43 percent improvement in median PFS in the overall patient population, compared to sorafenib. In a secondary endpoint,

objective response rates (either complete or partial responses assessed by independent central review) were more than doubled with axitinib compared to sorafenib in the overall patient population (19.4 percent vs 9.4 percent, P=0.0001). (Abstract #4503)

Consistent with previous analyses, axitinib demonstrated a generally manageable safety profile in this study. The study abstract lists the following common adverse events (all grade), which occurred more frequently in the axitinib arm compared to sorafenib: hypertension (40 percent), fatigue (39 percent), dysphonia (31 percent), and hypothyroidism (19 percent).

In an additional oral abstract evaluating patient-reported outcomes (PRO), a secondary endpoint of the AXIS study, patients treated with axitinib reported similar kidney cancer-specific quality of life scores compared to patients treated with sorafenib, and a delay in a pre-specified composite endpoint, which consisted of death, disease progression and worsening of quality of life. (Abstract #4504)

“These data, from the first head-to-head Phase 3 study comparing active targeted therapies in advanced RCC, are important for clinicians as they help us advance our understanding of this tumor, where there are limited proven options for previously-treated patients,” said Dr. Brian I. Rini, Taussig Cancer Institute at Cleveland Clinic, who served as principal investigator of this Pfizer-sponsored study and has been a paid consultant to Pfizer Oncology. “The clinically meaningful improvement in PFS seen with axitinib is even more encouraging as it was accompanied by generally manageable tolerability, an important consideration for these patients.”

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 Axitinib

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

Axitinib is also being investigated in a randomized Phase 3 clinical trial in patients with treatment-naïve as well as previously treated advanced RCC, and in a randomized Phase 2 clinical trial for the treatment of hepatocellular carcinoma (HCC).

Advancing the Science of Kidney Cancer

As a leader in the treatment of advanced RCC, Pfizer Oncology is dedicated to offering multiple 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 that 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, 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, including full prescribing information for SUTENT (sunitinib malate), please visit www.pfizer.com [http://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 ? 30%) are rash, asthenia, mucositis, nausea, edema, and anorexia. The most common laboratory abnormalities (incidence ? 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. 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 May 18, 2011. 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 the oncology product candidate axitinib, 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 axitinib 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, 2010 and in its reports on Form 10-Q and Form 8-K.

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