Pfizer Files For European Regulatory Review Of Axitinib For Patients With Advanced Renal Cell Carcinoma

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(BUSINESS WIRE)--Pfizer Inc. announced today that the European Medicines Agency (EMA) has accepted Pfizer's filing for regulatory review of axitinib for patients with advanced renal cell carcinoma (RCC) after failure of prior systemic treatment. This submission was based on Phase 3 data from the AXIS 1032 trial. Pfizer will present full results from this trial, as well as additional data on axitinib, at the 47th Annual Meeting of the American Society of Clinical Oncology (ASCO), being held in Chicago from June 3-7, 2011.

"While the prognosis for patients with advanced RCC has improved dramatically over the past five years thanks to the availability of new treatments, there is still a need for new options in this patient population," said Garry Nicholson, president and general manager, Pfizer Oncology Business Unit. "This regulatory filing for our innovative investigational therapy axitinib, as well as ongoing studies of our existing medications, underscores Pfizer's commitment to patients with advanced RCC and our leadership in helping physicians treat this disease."

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, 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 in any countries or jurisdictions.

Axitinib Clinical Research Program

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).

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 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. 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 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 June 1, 2011. The Company assumes no obligation to update forward-looking statements contained in this release as a result of new information or future events or developments.

This release contains forward-looking information about certain potential indications for the oncology product candidate 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 have been or may be filed for such indications as well as their decisions regarding labeling and other matters that could affect their 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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