FDA Advisory Committee Finds The Benefit/Risk Profile Of Axitinib In Previously Treated Advanced Renal Cell Carcinoma (RCC) To Be Favorable

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(BUSINESS WIRE)--Pfizer Inc. announced today that the U.S. Food and Drug Administration’s (FDA’s) Oncologic Drugs Advisory Committee (ODAC) voted unanimously 13 to 0 that data for the investigational agent axitinib support a favorable benefit/risk profile for the treatment of patients with advanced renal cell carcinoma (RCC) after failure of a first-line systemic therapy. The ODAC panel’s recommendation will be considered by the FDA when making its decision regarding Pfizer’s New Drug Application (NDA) for axitinib as a treatment for advanced RCC.

Approximately 58,000 new cases of RCC are diagnosed in the United States each year, and approximately 20 to 30 percent of these patients have advanced disease at the time of diagnosis. Around 13,000 individuals die of this tumor in the U.S. each year.

"We are pleased with the panel’s recommendation in support of axitinib for the treatment of previously treated advanced RCC, as additional therapeutic options are still needed for this patient population,” said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs, Pfizer Oncology Business Unit. “We look forward to continued discussions with the FDA as we take the next steps in the regulatory process

for axitinib.”

Axitinib is an oral therapy that was designed to selectively inhibit 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).

The ODAC panel members reviewed data on axitinib, including results from the Phase 3 AXIS trial of patients whose disease had progressed following treatment with one systemic therapy.

Axitinib has been widely studied in a broad clinical development program, evaluating its efficacy and safety in more than 2,500 patients across several tumor types. 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.

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.

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 includes two approved therapies for the treatment of people with advanced RCC.

For more information please visit www.Pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of December 7, 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 the FDA and other regulatory authorities regarding whether and when to approve drug applications that have been or may be filed for axitinib for the treatment of previously treated advanced RCC and any drug applications that may be filed for axitinib for other 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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