Pfizer Inc. UK Regulatory Announcement: Pfizer Initiates Rolling Submission For A New Drug Application In The U.S. For Its Fast-Tracked Investigational Compound Crizotinib (PF-02341066) For Patients With ALK-Positive Advanced Non-Small Cell Lung Cancer

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Company Anticipates Completing Submission in First Half of 2011 - - - Also Expects U.S. and Europe Filing of Two Other Investigational Oncology Compounds, Axitinib and Bosutinib, in 2011

(BUSINESS WIRE)--

Pfizer Inc. announced today that it has initiated the rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for crizotinib (PF-02341066), an oral first-in-class anaplastic lymphoma kinase (ALK) inhibitor for the treatment of patients with advanced non-small cell lung cancer (NSCLC) whose tumors are ALK-positive. Pfizer expects to complete the submission in the first half of 2011.

“This action represents a significant step in the registration process for crizotinib (PF-02341066). Pfizer is committed to working collaboratively with the FDA as we move forward in the submission process with the ultimate goal of offering a new treatment

option for patients with advanced ALK-positive NSCLC," said Garry Nicholson, president and general manager, Pfizer Oncology Business Unit.

The FDA's Fast Track process is designed to facilitate development and expedite review of drugs that treat serious or life-threatening diseases and demonstrate the potential to address unmet medical need.1 Pfizer was granted Fast Track designation by the FDA for crizotinib (PF-02341066) in December 2010. The rolling submission, which is available to medicines that have received Fast Track designation, allows completed portions of the crizotinib (PF-02341066) NDA to be submitted and reviewed by the FDA on an ongoing basis.

Crizotinib (PF-02341066) is an oral first-in-class compound that inhibits the anaplastic lymphoma kinase, or ALK.2 Alterations in the ALK gene are believed to be a key driver of tumor development in cancers like NSCLC, and approximately 3-5 percent of NSCLC tumors are ALK-positive.3 By inhibiting ALK, crizotinib (PF-02341066) blocks signaling in a number of cell pathways that are critical for the growth and survival of tumor cells.4 Crizotinib (PF-02341066) is also an inhibitor of c-MET (mesenchymal endothelial transition factor).3

Pfizer also plans regulatory submissions to the FDA and the European Medicines Agency for two other investigational oncology compounds in 2011 — axitinib, an oral and selective inhibitor of vascular endothelial growth factor (VEGF) receptors 1, 2 and 3, for the treatment of patients with metastatic renal cell carcinoma (mRCC), and bosutinib, an oral dual Src and Abl kinase inhibitor, for the treatment of chronic myeloid leukemia (CML).

About Non-Small Cell Lung Cancer

Worldwide, lung cancer is the leading cause of cancer death in men and the second leading cause of cancer death in women.5 NSCLC accounts for about 85 percent of lung cancer cases and remains difficult to treat, particularly in the metastatic setting. Approximately 75 percent of NSCLC patients are diagnosed late with metastatic, or advanced, disease, where the five-year survival rate is only 6 percent.6,7 In addition, the current standard of care for advanced NSCLC demonstrates a response rate of only about 15 percent.8

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.

Pfizer Inc.: Working together for a healthier world™

At Pfizer, 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 January 12, 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 candidates crizotinib, axitinib and bosutinib, including their potential benefits, the anticipated timing of the completion of the rolling submission for crizotinib and the anticipated timing of regulatory submissions for axitinib and bosutinib, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability of the Company to meet anticipated regulatory submission dates; decisions by regulatory authorities regarding whether and when to approve drug applications that have been or may be filed for such oncology product candidates as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such oncology

product candidates; 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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1 U.S. Food and Drug Administration. Fast Track, Accelerated Approval and Priority Review. Available at: http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantn. Accessed January 4, 2011.

2 Bang Y et al. Clinical Activity of the Oral ALK Inhibitor, Crizotinib (PF-02341066), in Patients with ALK-positive Non-Small Cell Lung Cancer. Accepted Plenary Presentation at the American Society of Clinical Oncology Annual Meeting, June 4-8, 2010. Chicago, IL.

3 Zou HY, Li Q, Lee JH, et al. An orally available small-molecule inhibitor of c-MET, PF-2341066, exhibits cytoreductive antitumor efficacy through antiproliferative and antiangiogenic mechanisms. Cancer Res. 2007;67:4408-4417.

4 Chiarle R, Voena C, Ambrogio C et al. The anaplastic lymphoma kinase in the pathogenesis of cancer. Nat Rev Cancer. 2008;8(1): 11-23.

5 American Cancer Society. Global Cancer Facts & Figures 2007. Atlanta, Ga: American Cancer Society: 2007.

6 Reade CA, Ganti AK. EGFR targeted therapy in non-small cell lung cancer: potential role of cetuximab. Biologics. 2009; 3: 215–224.

7 American Cancer Society. Detailed Guide: Lung Cancer (Non-Small Cell). Available at: http://files\pressrelease_assets\pdf\003115-pdf.pdf. Accessed August 26, 2010.

8 Huq S et al. Lung Cancer, Non-Small Cell: Treatment & Medication. Emedicine from WebMD. February 18, 2010. Available at: http://emedicine.medscape.com/article/279960-treatment. Accessed August 25, 2010.

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