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# Pfizer Announces Simultaneous Filing Of New Drug Applications For Crizotinib With U.S. Food And Drug Administration And Japanese Ministry Of Health, Labour And Welfare

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Crizotinib Submission Accepted for Filing and Granted Priority Review by FDA

(BUSINESS WIRE)--Pfizer Inc. announced today that its New Drug Application (NDA) for crizotinib, an oral first-in-class anaplastic lymphoma kinase (ALK) inhibitor, has been accepted for filing and granted Priority Review status by the U.S. Food and Drug Administration (FDA) and has been filed with the Japanese Ministry of Health, Labour and Welfare (MHLW). The proposed indication is for the treatment of patients with ALK-positive advanced non-small cell lung cancer (NSCLC).

“Our ability to file applications for regulatory review in the U.S. and Japan simultaneously only three years after beginning worldwide clinical trials in patients with ALK-positive lung cancer is a testament to the hard work of the crizotinib team and the productive discussions that we have had with the respective regulatory agencies. Given the clinical trial results seen to date, we believe that crizotinib, if approved, may change the treatment paradigm for patients with ALK-positive advanced NSCLC,” said Garry Nicholson, president and general manager, Pfizer Oncology Business Unit.

The FDA’s Priority Review status accelerates the review time from 10 months to a goal of six months and is given to drugs that may offer major advances in treatment or may provide a treatment where no adequate therapy exists.[1]

Crizotinib received orphan drug designation from the FDA in September 2010 and was granted Fast Track status in December 2010. As a result of the Fast Track designation, Pfizer initiated a rolling submission of crizotinib in January 2011. 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] In Japan, Pfizer commenced crizotinib clinical trials for patients with ALK-positive advanced NSCLC in March 2010, and crizotinib was granted orphan drug status in January 2011. These filings represent the first simultaneous filings in Japan and the U.S. for a non-Japanese-based pharmaceutical company.

Crizotinib is an investigational 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.[3] The presence of the ALK fusion gene in lung cancer was first reported by a Japanese researcher in 2007. Preliminary epidemiology suggests that approximately 3–5 percent of NSCLC patients have tumors that

are positive for the ALK fusion gene. By inhibiting ALK, crizotinib blocks signaling in a number of cell pathways that are believed to be critical for the growth and survival of tumor cells.

**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.[4] 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.[5,6] In addition, the current standard of care for advanced NSCLC demonstrates a response rate of about 15-35 percent.[7]

**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.

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*DISCLOSURE NOTICE: The information contained in this release is as of May 17, 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 crizotinib, 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 in the U.S., Japan and other jurisdictions regarding whether and when to approve drug applications that have been or may be filed for crizotinib 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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[1] U.S. Food and Drug Administration. *Fast Track, Accelerated Approval and Priority Review.* Available at: http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantnewtherapies/ucm128291.h . 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] American Cancer Society. Global Cancer Facts & Figures 2007. Atlanta, Ga: American Cancer Society: 2007.

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

[6] American Cancer Society. *Detailed Guide: Lung Cancer (Non-Small Cell).* Available at: \files\pressrelease_assets\pdf\003115-pdf_5.pdf. Accessed August 26, 2010.

[7] 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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