

Pfizer Announces European Medicines Agency Acceptance of Regulatory Submissions For Two Investigational Cancer Therapies

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Submission Accepted for Crizotinib, Pfizer's ALK-Targeted Therapy for Patients with Previously Treated ALK-Positive Advanced Non-Small Cell Lung Cancer Submission Accepted for Bosutinib for Patients with Newly Diagnosed Philadelphia Chromosome Positive Chronic Myeloid Leukemia

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[\(BUSINESS WIRE\)](#)--Pfizer Inc. announced today that the European Medicines Agency (EMA) has accepted Pfizer's regulatory submissions for review of two investigational compounds - crizotinib, an oral first-in-class anaplastic lymphoma kinase (ALK) inhibitor, for the treatment of patients with previously treated ALK-positive advanced non-small cell lung cancer (NSCLC); and bosutinib for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in the chronic phase.

"With the EMA submissions for crizotinib and bosutinib, we are one step closer to potentially bringing two promising agents to patient populations in areas of significant unmet medical need," said Dr. Andreas Penk, president of Pfizer Oncology Europe. "These filings underscore Pfizer's commitment to delivering innovative therapeutic treatment options targeting various tumor types and improving the outcome for cancer patients worldwide."

About Crizotinib

In clinical trials of crizotinib, patients were prospectively screened for the ALK gene alteration, indicating their likelihood to respond to the treatment. 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.¹ Preliminary epidemiology suggests that approximately 3-5 percent of NSCLC tumors are ALK-positive.^{2,3,4,5,6,7,8,9}

Crizotinib is being further evaluated in two randomized Phase 3 trials in patients with ALK-positive NSCLC: PROFILE 1014 and PROFILE 1007 will compare the safety and efficacy of crizotinib to standard-of-care chemotherapy as a first-line and second-line therapy, respectively.^{10,11}

For more information on how to enroll in a crizotinib clinical trial, contact the Pfizer Oncology Clinical Trial Information Service: call 1-877-369-9753 (US/Canada) email PfizerHPTrials@emergingmed.com or visit www.pfizercancertrials.com.

Worldwide, lung cancer is the leading cause of cancer death in both men and women.¹² In Europe, lung cancer accounts for 20 percent of all cancer-related deaths.¹³ 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.^{14,15} In addition, the current standard of care for patients with advanced NSCLC demonstrates a response rate of about 9-35 percent.^{16,17}

About Bosutinib

Bosutinib is an investigational oral dual Src and Abl kinase inhibitor with minimal inhibitory activity against c-kit and PDGFR.¹⁸ It is believed that by dual inhibition of the Src and Abl tyrosine kinases, bosutinib may inhibit signaling in CML cells that allows the cells to grow, survive and reproduce.¹⁹

Chronic myeloid leukemia (CML), one of the four main types of leukemia,²⁰ accounts for 15 percent of all leukemias worldwide.²¹ A hallmark of CML is an abnormal chromosome known as the Philadelphia Chromosome, a DNA mutation that initiates a series of events leading to the development of Bcr-Abl, a tyrosine kinase that causes CML cells to grow and reproduce rapidly.²²

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 August 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 two oncology product candidates, crizotinib and bosutinib, 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 drug applications that have been or may be filed

for these oncology product candidates 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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