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Pfizer Plans Regulatory Submissions of Bosutinib in Chronic Myeloid Leukemia

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NEW YORK--(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today it is planning regulatory submissions of bosutinib in patients with chronic myeloid leukemia (CML) based on data from a clinical program evaluating the compound in newly diagnosed and previously treated patients. These regulatory submissions are planned for 2011.

Pfizer has begun the process of preparing a Marketing Authorization Application (MAA) for submission to the European Medicine Agency (EMA) for bosutinib as a treatment option for patients with newly diagnosed Philadelphia chromosome positive (Ph+) CML. The submission will be based on the results of the ongoing, Phase 3, randomized, open-label study of bosutinib versus imatinib in newly diagnosed patients with chronic phase Ph+ CML, called the BELA (**B**osutinib **E**fficacy and safety in chronic myeloid **L**eukemi**A**) study.(1)

The Company has also had discussions with the United States (U.S.) Food and Drug Administration (FDA) regarding a possible regulatory submission for the use of bosutinib in the treatment of previously treated Ph+ CML patients. This submission would be based on the pending 24-month efficacy and safety data in the primary cohort of Study 200, which consists of more than 200 previously treated CML patients. Study 200 is a single arm study of bosutinib in over 500 patients with previously treated Ph+ CML, including patients resistant or intolerant to imatinib as well as patients who have become refractory to dasatinib or nilotinib.(2) Currently, there are no approved therapies available for CML patients who fail dasatinib or nilotinib in second line.(3,4,5)

"We are excited about the potential opportunities to bring bosutinib to market for patients with CML given the need for options in this patient population," said Garry Nicholson, president and general manager of the Pfizer Oncology business unit. "Our ongoing analysis of the bosutinib clinical development program reinforces our belief that bosutinib may provide benefit for patients living with CML, and we are working closely with health authorities and other experts toward our goal of making this promising compound available to patients who need it."

Further details of the BELA study and Study 200 will be presented at the upcoming 52nd Annual Meeting of the American Society of Hematology (ASH) (Abstract #208,(1) December 6 and Abstract #892,(2) December 7, respectively).

About Bosutinib

Bosutinib is an investigational oral dual Src and Abl kinase inhibitor.(1) 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.(6)

About Chronic Myeloid Leukemia

Chronic myeloid leukemia (CML), one of the four main types of leukemia,(7) accounts for 15 percent of all leukemias worldwide.(8) 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.(9)

Pfizer's Commitment to Hematology

Pfizer Oncology is committed to developing therapies to treat a variety of hematologic malignancies in both adult and pediatric patient populations. Collectively, hematologic cancers represent the fifth most commonly occurring cancers and the second leading cause of cancer death. While there have been significant advancements in the treatment of hematologic cancers, there continues to be a need for new therapeutic approaches, both for newly diagnosed patients and relapsed patients. In order to deliver new options that target specific hematologic abnormalities and mutations, it is important to understand the molecular subtypes and genetic variations associated with hematologic cancers. Pfizer Oncology has biologics and small molecules in clinical development across a number of hematologic malignancies.

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 December 3, 2010. 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 certain potential indications for bosutinib, an oncology product candidate, including their potential benefits and the planned timing of regulatory submissions for such indications, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development, including with regard to the pending 24-month data from Study 200 and the ability of the Company to meet anticipated regulatory submission dates; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for any 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, 2009 and in its reports on Form 10-Q and Form 8-K.

(1) ASH Accepted Abstract #208. An Ongoing Phase 3 Study of Bosutinib (SKI-606) Versus Imatinib In Patients with Newly Diagnosed Chronic Phase Chronic Myeloid Leukemia. Oral Presentation. Carlo Gambacorti- Presenter. 52nd American Society of Hematology Annual Meeting. Orlando, FL. December 4-7, 2010

(2) ASH Accepted Abstract #892. Bosutinib as Third-Line Treatment for Chronic Phase Chronic Myeloid Leukemia Following Failure of Second-Line Therapy with Dasatinib or Nilotinib. Oral Presentation. H. J. Khoury - Presenter. 52nd American Society of Hematology Annual Meeting. Orlando, FL. December 4-7, 2010.

(3) GLEEVEC. Prescribing Information. Novartis. East Hanover, NJ. 2010.

(4) SPRYCEL Prescribing Information. Bristol-Myers Squibb. Princeton, NJ. 2010.

(5) TASIGNA Prescribing Information. Novartis. East Hanover, NJ. 2007.

(6) Konig H et al. Effects of Dasatinib on Src Kinase Activity and Downstream Intracellular Signaling in Primitive Chronic Myelogenous Leukemia Hematopoietic Cells. *Cancer Research*. 2008; 68: 9624-9633.

(7) National Cancer Institute. What you need to know about leukemia – Types of Leukemia. Available here: http://www.cancer.gov/cancertopics/wyntk/leukemia/page3. Accessed November 16, 2010.

(8) Jabbour E et al. Targeted Therapy in Chronic Myeloid Leukemia. *Expert Review of Anticancer Therapy*. 2008; 8: 99-110.

(9) American Cancer Society. Detailed Guide: Leukemia – Chronic Myeloid (Myelogenous). Available at: files\pressrelease_assets\pdf\003112-pdf_3.pdf. Accessed November 16, 2010.

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