Pfizer Announces FDA Acceptance Of New Drug Application For Bosutinib For Patients With Previously Treated Ph+ Chronic Myeloid Leukemia

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--(BUSINESS WIRE)--Pfizer Inc. announced today that the U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) for standard review of bosutinib as a treatment option for adult patients with previously treated Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML). This submission was based on efficacy and safety data from Study 200, 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 were previously treated with dasatinib or nilotinib. Currently, there are no approved therapies available for CML patients after second-line treatment with dasatinib or nilotinib.

CML, one of the four main types of leukemia,1 accounts for 15 percent of all leukemias worldwide.2 Despite the availability of existing treatments, there remains a need for additional options for CML patients, given observed treatment–related toxicities and resistance.

“This filing underscores our commitment to bringing innovative treatment options to hematologic patient populations like CML, where the need for additional treatment

options exists,” said Garry Nicholson, president and general manager of the Pfizer Oncology Business Unit. “We are excited about the potential to bring this promising agent to those patients who fail or progress on previous therapies.”

Bosutinib is an oral, once-daily, investigational dual Src and Abl kinase inhibitor with minimal inhibitory activity against c-kit and PDGFR.3 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.4

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.5 In some cases, resistance may develop to currently available therapies that inhibit Bcr-Abl.6 Inhibition of both Src and Abl tyrosine kinases may help overcome this resistance,7 as overexpression of the Src family of tyrosine kinases has been implicated in resistance and CML progression.4

Pfizer's Commitment to Hematology

Hematologic cancers are a complex group of diseases, with over 70 different types of lymphomas, leukemias or myelomas. While there have been significant advancements in the treatment of some hematologic cancers, there continues to be a need for additional therapeutic options. Pfizer Oncology is committed to improving outcomes for patients living with hematologic malignancies like CML. Pfizer Oncology has a robust hematology pipeline, with biologics and small molecules in clinical development across a number of hematologic malignancies. We are advancing technologies as well as working to identify new and innovative options that address specific hematologic cancers, molecular subtypes, gene over-expression and mechanisms of resistance.

Pfizer Oncology is committed to the discovery, investigation and development of innovative treatment options to improve the outlook for cancer patients worldwide. For more information, please visit www.Pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of January 27, 2012. 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 an oncology product candidate, bosutinib, 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 the FDA, the EMA and other regulatory authorities regarding whether and when to approve drug applications that have been or may be filed for bosutinib, 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.

1 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.

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

3 Gambacorti-Passerini C et al. Bosutinib (SKI-606) Demonstrates Clinical Activity and is Well Tolerated in Patients with AP and BP CML and Ph+ ALL. Poster Presented at the American Society of Hematology Meeting, December 6-9, 2008, San Francisco, CA. Wyeth.

4 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.

5 American Cancer Society. Detailed Guide: Leukemia – Chronic Myeloid (Myelogenous). Available at: http://files\pressrelease_assets\pdf\003112-pdf_2.pdf. Accessed November 16, 2010.

6 Redaelli S. Activity of Bosutinib, Dasatinib, and Nilotinib Against 18 Imatinib-Resistant BCR/ABL Mutants. Journal of Clinical Oncology. 2008; 27: 1-3.

7 CenterWatch. Drug Information: Sprycel. CenterWatch. Available at: http://www.centerwatch.com/drug-information/fda-approvals/drug-details.aspx?DrugID=903. Accessed January 15, 2010.

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