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Pfizer’s BOSULIF® (bosutinib) Receives Conditional Marketing Authorization From The European Commission

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(BUSINESS WIRE)--Pfizer Inc. announced today that the European Commission (EC) has granted conditional marketing authorization for BOSULIF® (bosutinib) in the European Union (EU) for the treatment of adult patients with chronic phase (CP), accelerated phase (AP) and blast phase (BP) Philadelphia chromosome positive chronic myelogenous leukemia (Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) (TKIs) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.[1]

“I’m delighted the EC has approved BOSULIF as a new addition to the CML treatment landscape in Europe,” said Carlo Gambacorti-Passerini, MD, Professor of Internal Medicine at the University of Milano Bicocca in Italy, Director of the Clinical Research Unit, Section of Hematology at S. Gerardo Hospital in Monza, Italy, and a lead investigator in the BOSULIF clinical study. “It’s critical to have additional treatment options for CML patients, because each patient responds to therapy differently and has unique needs. Based on my experience with BOSULIF, I believe this once-daily treatment, with its distinct safety profile, offers an important new alternative.”

Conditional marketing authorizations in the EU are granted to medicinal products with a positive benefit/risk assessment that address unmet medical needs and whose availability would result in a significant public health benefit. A conditional marketing authorization is renewable annually. As part of the conditional approval, Pfizer is committed to generating additional efficacy and safety data for BOSULIF in patients with Ph+ CML previously treated with one or more TKIs not suitable for imatinib, dasatinib and nilotinib, and will submit the findings to the European Medicines Agency (EMA). Following review of the data by the EMA’s Committee for Medicinal Products for Human Use (CHMP), the EC will consider converting the conditional marketing authorization to a full marketing authorization.

The EC decision was based on data from Study 200, a global, single-arm, open-label, multi-cohort, Phase 1/2 study of BOSULIF in more than 500 patients with Ph+ CML who had previously been treated with at least one TKI. The study included separate cohorts for patients with chronic, accelerated and blast phase disease. Data on 52 patients were considered as main evidence for the conditional marketing authorization, as these patients were identified as having an unmet medical need because other TKIs were not considered appropriate treatment options for them due to disease resistance or the risk of severe side effects.

“The approval of BOSULIF reflects the progress that is being made to address the unmet needs of CML patients in Europe and exemplifies Pfizer’s commitment to bringing meaningful new medicines to patients living with hematologic malignancies,” said Andreas Penk, Regional President of Europe for the Pfizer Oncology Business Unit.

About BOSULIF (bosutinib)

BOSULIF is an oral, once-daily, kinase inhibitor, which limits cancer cell growth by inhibiting the Abl and Src signaling pathways.[2] The recommended dose of BOSULIF is 500 mg, orally, taken once daily with food.[1] BOSULIF was first approved in the U.S. in September 2012 for the treatment of adult patients with chronic, accelerated or blast phase Ph+ CML with resistance, or intolerance, to prior therapy.[3]

Important BOSULIF (bosutinib) U.S. Safety Information

Contraindication: Hypersensitivity to BOSULIF. Anaphylactic shock occurred in less than 0.2% of treated patients.

Gastrointestinal Toxicity: Diarrhea, nausea, vomiting, and abdominal pain can occur. In the clinical trial, median time to onset for diarrhea was 2 days, median duration was 1 day, and median number of episodes per patient was 3 (range 1-221). Monitor and manage patients using standards of care, including antidiarrheals, antiemetics, and/or fluid replacement. Withhold, dose reduce, or discontinue BOSULIF as necessary.

Myelosuppression: Thrombocytopenia, anemia, and neutropenia can occur. A complete blood count should be performed weekly for the first month and then monthly or as clinically indicated. Withhold, dose reduce, or discontinue BOSULIF as necessary.

Hepatic Toxicity: Twenty percent of patients experienced an increase in either alanine aminotransferase (ALT) or aspartate aminotransferase (AST). Liver enzyme elevation usually occurs early in treatment. Perform monthly hepatic enzyme tests for the first 3 months and as clinically indicated. In patients with transaminase elevations, monitor liver enzymes more frequently. Drug-induced liver injury has occurred. Withhold, dose reduce, or discontinue BOSULIF as necessary.

Fluid Retention: Fluid retention can occur and may cause pericardial effusion, pleural effusion, pulmonary edema, and/or peripheral edema. Monitor and manage patients using standards of care. Interrupt, dose reduce, or discontinue BOSULIF as necessary.

Embryofetal Toxicity: BOSULIF may cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised of potential hazard to the fetus and to avoid becoming pregnant while receiving BOSULIF.

Adverse Reactions: The most common adverse reactions observed in greater than 20% of patients in the Phase 1/2 safety population (N=546) were diarrhea, nausea, thrombocytopenia, vomiting, abdominal pain, rash, anemia, pyrexia, and fatigue.

The most common Grade 3/4 adverse reactions and laboratory abnormalities observed in greater than 10% of patients were thrombocytopenia, anemia, and neutropenia.

Drug Interactions: Avoid concurrent use with strong or moderate CYP3A inhibitors or inducers.

Proton Pump Inhibitors (PPIs): Consider using short-acting antacids or H2 blockers instead of PPIs. Separate antacid or H2 blocker dosing and BOSULIF dosing by more than 2 hours.

Substrates of P-glycoprotein: BOSULIF may increase the plasma concentrations of drugs that are P-gp substrates, such as digoxin.

Nursing Mothers: Given the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or BOSULIF.

Hepatic Impairment: Treat with a dose of 200 mg daily in patients with any baseline hepatic impairment.

For more information and full prescribing information, please visit www.pfizer.com.

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.

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.

For more information, please visit www.Pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of March 28, 2013. 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 that involves substantial risks and uncertainties about an oncology product, BOSULIF. Such risks and uncertainties include, among other things, whether and when the European Commission (EC) will convert the conditional marketing authorization for BOSULIF to a full marketing authorization in the EU, as well as the EC's decisions regarding labeling and other matters that could affect BOSULIF's availability or commercial potential in the EU; 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, 2012 and in its reports on Form 10-Q and Form 8-K.

[1] Summary of Product Characteristics (SmPC) for BOSULIF®. Sandwich, Kent: UK; 2013.

[2] Konig H. Effects of Dasatinib on Src Kinase Activity and Downstream Intracellular Signaling in Primitive Chronic Myelogenous Leukemia Hematopoietic Cells. *Cancer Research*. 2008; 68: 9624-9633.

[3] BOSULIF® (bosutinib) Prescribing Information. New York, NY: Pfizer, Inc.; 2012.

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