Pfizer and Avillion Announce Positive Top-Line Results for Phase 3 BFORE Study of BOSULIF for First-Line Treatment of Philadelphia Chromosome Positive Chronic Myeloid Leukemia

NEW YORK, N.Y., December 5, 2016 – Today, Pfizer Inc. and its partner Avillion LLP announced results from the Phase 3 BFORE (**B**osutinib trial in **F**irst line chr**O**nic myelogenous leukemia t**RE**atment) trial demonstrating superiority of BOSULIF® (bosutinib) over imatinib as a first-line treatment for patients with chronic phase Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML). The study met its primary endpoint of major molecular response (MMR) at 12 months. No new or unexpected safety issues were identified. BOSULIF is currently indicated in the U.S. and EU for the treatment of adult patients with Ph+ CML with resistance or intolerance to prior therapy.

"Since its approval, the efficacy and distinct tolerability profile of BOSULIF has provided an important treatment option for patients with Ph+ CML who are resistant or intolerant to prior therapy. The positive outcome of the BFORE study represents a key step in potentially broadening treatment options for patients in the first-line setting," said Mace Rothenberg, MD, chief development officer, Oncology, Pfizer Global Product Development. "This is an important milestone for Pfizer's emerging hematology portfolio as we work to develop new treatments for patients with acute and chronic hematologic malignancies."

"This successful partnership between Pfizer and Avillion is good news for CML patients because additional first-line treatment options allow physicians to tailor therapy based on individual patient considerations," said Allison Jeynes-Ellis, MD, Chief Executive Officer of Avillion. "The outcome of this partnership reinforces our belief in the potential of our innovative business model for the co-development and partnership of late-stage clinical candidates."

Based on the results of the study, Pfizer will work with the U.S. Food and Drug Administration (FDA) and other regulatory authorities to potentially make BOSULIF available for Ph+ CML patients in the first-line setting. Detailed efficacy and safety data from this study will be submitted for a future congress or peer-reviewed journal.

Pfizer and Avillion entered into an exclusive collaborative development agreement in 2014 to conduct the BFORE trial. Under the terms of the agreement, Avillion provided funding and conducted the trial to generate the clinical data that will be used to support potential regulatory filings for marketing authorization of BOSULIF as first-line treatment of patients with chronic phase Ph+ CML. If approved for this indication, Avillion will be eligible to receive milestone payments from Pfizer. Pfizer retains all rights to commercialize BOSULIF globally.

Pfizer is advancing a broad range of therapies that leverage select pathways and mechanisms of action to address acute and chronic leukemias, myeloproliferative disorders and lymphoma.

About the BFORE Study

BFORE (**B**osutinib trial in **F**irst line chr**O**nic myelogenous leukemia t**RE**atment) is a multi-center, open-label Phase 3 study designed to assess the effectiveness and safety of BOSULIF® (bosutinib) as a first-line treatment for patients with chronic phase Ph+ CML. The study enrolled 536 patients at multiple sites in North America, Asia and Europe. Patients were randomized 1:1 to receive BOSULIF 400mg or imatinib, a standard of care, for the duration of the study. The primary outcome was to show superiority of bosutinib over imatinib at 12 months by comparing MMR, or the proportion of patients in each arm whose levels of the Bcr-Abl1 kinase have dropped below 0.1%.

ABOUT BOSULIF® (bosutinib)

BOSULIF® (bosutinib) is an oral, once-daily, tyrosine kinase inhibitor (TKI), which inhibits the Bcr-Abl kinase that promotes CML; it is also an inhibitor of Src-family kinases. BOSULIF® was approved in September 2012 in the U.S. for the treatment of adult patients with Ph+ CML with resistance or intolerance to prior therapy and offers an important treatment option for these patients. In Europe, BOSULIF was granted conditional marketing authorization in March 2013 for the treatment of adult patients with Ph+ CML previously treated with one or more TKIs and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options. The current approved dose of BOSULIF® is 500 mg orally once daily with food. For more information on BOSULIF resources available for healthcare professionals and patients, please visit www.BOSULIF.com.

IMPORTANT BOSULIF® (bosutinib) 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. Perform complete blood counts 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 ALT or AST. Liver enzyme elevation usually occurs early in treatment. Perform hepatic enzyme tests monthly 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. In patients with mild, moderate, or severe hepatic impairment, the recommended starting dose is 200 mg daily.

Renal Toxicity: An on-treatment decline in estimated glomerular filtration rate has occurred in patients treated with BOSULIF. Monitor renal function at baseline and during therapy, with particular attention to patients with preexisting renal impairment or risk factors. Consider dose adjustment in patients with baseline and treatment emergent renal impairment. The recommended starting doses for patients with severe renal impairment (CrCL <30 mL/min) or moderate renal impairment (CrCL 30-50 mL/min) are 300 mg and 400 mg daily, respectively.

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.

CYP3A Inhibitors and Inducers: Avoid concurrent use with strong or moderate CYP3A inhibitors or inducers.

Proton Pump Inhibitors: Consider using short-acting antacids or H2 blockers instead of PPIs to avoid a reduction in BOSULIF exposure. Separate antacid or H2 blocker dosing and BOSULIF dosing by more than 2 hours.

Nursing Mothers: Given the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or BOSULIF, taking into account the importance of the drug to the mother.

Please see full Prescribing Information at www.bosulif.com.

ENDS

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