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

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Today, Pfizer Inc. and its partner Avillion LLP announced results from the Phase 3 BFORE (Bosutinib trial in First line chrOnic myelogenous leukemia tREatment) 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 (Bosutinib trial in First line chrOnic myelogenous leukemia tREatment) 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.

About Pfizer Oncology

Pfizer Oncology is committed to pursuing innovative treatments that have a meaningful impact on those living with cancer. As a leader in oncology speeding cures and accessible breakthrough medicines to patients, Pfizer Oncology is helping to redefine life with cancer. Our strong pipeline of biologics, small molecules and immunotherapies is one of the most robust in the industry, and is studied with precise focus on identifying and translating the best scientific breakthroughs into clinical application for patients across a wide range of cancers. By working collaboratively with academic institutions, individual

researchers, cooperative research groups, governments and licensing partners, Pfizer Oncology strives to cure or control cancer with its breakthrough medicines. Because Pfizer Oncology knows that success in oncology is not measured solely by the medicines you manufacture, but rather by the meaningful partnerships you make to have a more positive impact on people’s lives. Learn more about how Pfizer Oncology is applying innovative approaches to improve the outlook for people living with cancer at http://www.pfizer.com/research/therapeutic_areas/oncology.

Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @PfizerNews, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

About Avillion

Avillion LLP is a drug development company with an innovative business model focusing on the clinical co-development and regulatory approval of late stage pharmaceutical products. Avillion offers a compelling opportunity to partner late-stage therapeutic projects for approval in the US and EU and to accelerate their availability to the market. Our objective is to enable our partners to continue to develop the drug candidates in their pipeline at the highest quality without increasing the burden on their P&L or cash reserves. Avillion can achieve this by incurring 100% of the clinical and regulatory risk, while advancing the development of these late-stage assets in return for milestone payments on the commercialisation of successfully developed products.

Avillion was founded in 2012 in London, UK, and is backed by Abingworth, Clarus Ventures and Royalty Pharma. http://www.avillionllp.com

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of December 5, 2016. 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 BOSULIF (bosutinib), including a potential new indication for BOSULIF for the first-line treatment for patients with Ph+ CML, and its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including, without limitation, the ability to meet anticipated trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; uncertainties regarding the commercial success of BOSULIF; whether and when any applications for the potential new indication may be filed with regulatory authorities in any jurisdictions; whether and when regulatory authorities in any jurisdictions may approve such applications, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of BOSULIF, including for the potential new indication; 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, 2015 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned “Risk Factors” and “Forward-Looking Information and Factors That May Affect Future Results”, as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at www.sec.gov and www.pfizer.com.

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