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Pfizer Receives Positive CHMP Opinion for Two Hematology Medicines, MYLOTARG™ and BOSULIF®

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MYLOTARG (gemtuzumab ozogamicin) Granted a Positive Opinion for the Treatment of Previously Untreated, De Novo, CD33-positive Acute Myeloid Leukemia in Combination with Chemotherapy BOSULIF (bosutinib) Granted a Positive Opinion for the Treatment of Newly Diagnosed Ph+ Chronic Myelogenous Leukemia

Pfizer Inc. (NYSE:PFE) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted positive opinions recommending that two Pfizer hematology medicines be granted marketing authorizations in the European Union (EU). MYLOTARG™ (gemtuzumab ozogamicin) in combination with daunorubicin and cytarabine has been granted a positive opinion for the treatment of patients age 15 years and above with previously untreated, de novo, CD33-positive acute myeloid leukemia (AML), except acute promyelocytic leukemia (APL). BOSULIF® (bosutinib) has been granted a positive opinion for the treatment of adults with newly diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML). The CHMP's opinions for both medicines will now be reviewed separately by the European Commission (EC).

"There is an urgent need to improve outcomes for leukemia patients in Europe," said Mace Rothenberg, M.D., chief development officer, Oncology, Pfizer Global Product Development. "If approved, the addition of MYLOTARG to standard chemotherapy will provide an important new treatment option for patients with acute myeloid leukemia who would typically be treated with chemotherapy alone. Additionally, the potential expansion of the approved use of BOSULIF to include first-line therapy expands the treatment options for adult patients with newly diagnosed chronic myelogenous leukemia."

The Marketing Authorization Application (MAA) for MYLOTARG was based on data from an investigator-led, Phase 3, randomized, open-label study (ALFA-0701) in previously untreated, de novo patients.

BOSULIF currently has conditional marketing authorization in Europe related to the initial marketing authorization. The Type II Variation application for BOSULIF for adults with newly diagnosed chronic phase Ph+ CML was based on results from BFORE (Bosutinib trial in First line chrOnic myelogenous leukemia tREatment), a randomized multicenter, multinational, open-label, Phase 3, head-to-head study of BOSULIF 400 mg versus imatinib 400 mg, a current standard of care.

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 for the trial to generate the clinical data used to support this application and other potential regulatory filings for marketing authorization for BOSULIF as first-line treatment for patients with chronic phase Ph+ CML. Pfizer retains all rights to commercialize BOSULIF globally.

IMPORTANT MYLOTARG™ (gemtuzumab ozogamicin) SAFETY INFORMATION FROM THE U.S. PRESCRIBING INFORMATION

WARNING: Hepatotoxicity, including severe or fatal hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), has been reported in association with the use of MYLOTARG as a single agent, and as part of a combination chemotherapy regimen. Monitor frequently for signs and symptoms of VOD after treatment with MYLOTARG.

Hepatotoxicity, Including Veno-occlusive Liver Disease (VOD): An increased risk of VOD was observed in patients with moderate/severe hepatic impairment and patients who received MYLOTARG either before or after HSCT. Assess ALT, AST, total bilirubin, and alkaline phosphatase prior to each dose of MYLOTARG. After treatment with MYLOTARG, monitor frequently for signs and symptoms of VOD; these may include elevations in ALT, AST, and total bilirubin, hepatomegaly, rapid weight gain, and ascites. Monitoring only total bilirubin may not identify all patients at risk of VOD. For patients who develop abnormal liver tests, more frequent monitoring of liver tests and clinical signs and symptoms of hepatotoxicity is recommended. For patients who proceed to HSCT, monitor liver tests frequently during the post-HSCT period, as appropriate. Manage signs or symptoms of hepatic toxicity by dose interruption or discontinuation of MYLOTARG. In patients who experience VOD, discontinue MYLOTARG and treat according to standard medical practice.

Infusion-Related Reactions (Including Anaphylaxis): Life-threatening or fatal infusion-related reactions can occur during or within 24 hours following infusion of MYLOTARG. Signs and symptoms of infusion-related reactions may include fever, chills, hypotension, tachycardia, hypoxia, and respiratory failure. Premedicate prior to MYLOTARG infusion. Monitor vital signs frequently during infusion. Interrupt infusion immediately for patients who develop evidence of infusion reaction, especially dyspnea, bronchospasm, or hypotension. Monitor patients during and for at least 1 hour after the end of the infusion or until signs and symptoms completely resolve. Discontinue use of MYLOTARG in patients who develop signs or symptoms of anaphylaxis, including severe respiratory symptoms or clinically significant hypotension.

Hemorrhage: MYLOTARG is myelosuppressive and can cause fatal or life-threatening hemorrhage due to prolonged thrombocytopenia. Assess blood counts prior to each dose of MYLOTARG and monitor blood counts frequently after treatment with MYLOTARG until resolution of cytopenias. Monitor patients for signs and symptoms of bleeding during treatment with MYLOTARG. Manage severe bleeding, hemorrhage, or persistent thrombocytopenia using dose delay or permanent discontinuation of MYLOTARG, and provide supportive care per standard practice.

QT Interval Prolongation: QT interval prolongation has been observed in patients treated with other drugs containing calicheamicin. When administering MYLOTARG to patients who have a history of or predisposition for QTc prolongation, who are taking medicinal products that are known to prolong QT interval, and in patients with electrolyte disturbances, obtain electrocardiograms and electrolytes prior to the start of treatment and as needed during administration.

Adverse Cytogenetics: In a subgroup analysis in ALFA-0701, the addition of MYLOTARG to standard combination chemotherapy did not improve event-free survival in the subgroup of patients having adverse-risk cytogenetics. For patients being treated with MYLOTARG in combination with daunorubicin and cytarabine for newly diagnosed de novo AML, when cytogenetics testing results become available consider whether the potential benefit of continuing treatment with MYLOTARG outweighs the risks for the individual patient.

Embryo-Fetal Toxicity: MYLOTARG can cause embryo-fetal harm when administered to a pregnant woman. Advise patients of reproductive potential to use effective contraception during and for 3 and 6 months following treatment for males and females, respectively. Apprise pregnant women of the potential risk to the fetus. Advise

women to contact their healthcare provider if they become pregnant or if pregnancy is suspected during treatment with MYLOTARG.

Adverse Reactions: The most common adverse reactions (greater than 15%) were hemorrhage, infection, fever, nausea, vomiting, constipation, headache, increased AST, increased ALT, rash, and mucositis.

Contraindications: Hypersensitivity to MYLOTARG or any of its components. Reactions have included anaphylaxis.

The full U.S. prescribing information, including BOXED WARNING, for MYLOTARG can be found here.

IMPORTANT BOSULIF® (bosutinib) SAFETY INFORMATION FROM THE U.S. PRESCRIBING INFORMATION

Contraindication: History of hypersensitivity to BOSULIF. Reactions have included anaphylaxis. Anaphylactic shock occurred in less than 0.2% of treated patients in single-agent cancer studies with BOSULIF.

Gastrointestinal Toxicity: Diarrhea, nausea, vomiting, and abdominal pain can occur. In the randomized clinical trial of patients with newly diagnosed Ph+ CML, the median time to onset for diarrhea (all grades) among patients in the BOSULIF treatment group (n=268) was 3 days and the median duration per event was 3 days. Among 546 patients in a single-arm study of patients with CML who were resistant or intolerant to prior therapy, median time to onset of diarrhea (all grades) was 2 days, median duration was 2 days, and the median number of episodes per patient was 3 (range 1-268). 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 monthly thereafter, or as clinically indicated. Withhold, dose reduce, or discontinue BOSULIF as necessary.

Hepatic Toxicity: Elevations in serum transaminases (alanine aminotransferase [ALT] and aspartate aminotransferase [AST]) can occur. Perform hepatic enzyme tests at least monthly for the first 3 months and as clinically indicated. In patients with transaminase elevations, monitor liver enzymes more frequently. One case consistent with drug-induced liver injury occurred without alternative causes in a trial of BOSULIF in combination with letrozole. 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 for renal dysfunction. Consider dose adjustment in patients with baseline and treatment-emergent renal impairment.

Reduce the BOSULIF starting dose in patients with moderate (creatinine clearance [CLcr] 30 to 50 mL/min) or severe (CLcr less than 30 mL/min) renal impairment at baseline. For patients who have declining renal function while on BOSULIF who cannot tolerate the starting dose, follow dose adjustment recommendations for toxicity.

Fluid Retention: Fluid retention can occur with BOSULIF and may cause pericardial effusion, pleural effusion, pulmonary edema, and/or peripheral edema. Among 546 patients in a single-arm study of patients with Ph+ CML who were resistant or intolerant to prior therapy, Grade 3/4 fluid retention was reported in 26 patients (5%). Monitor and manage patients using standards of care. Interrupt, dose reduce, or discontinue BOSULIF as

necessary.

Embryofetal Toxicity: BOSULIF can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised of the potential hazard to the fetus. Advise females of reproductive potential to use effective contraceptive measures to prevent pregnancy while being treated with BOSULIF and for at least 1 month after the final dose.

Adverse Reactions: The most common adverse reactions observed in greater than or equal to 20% of patients with newly diagnosed CML were diarrhea, nausea, thrombocytopenia, rash, increased ALT, abdominal pain, and increased AST. The most common Grade 3/4 adverse reactions and laboratory abnormalities observed in greater than 10% of newly diagnosed CML patients were thrombocytopenia and increased ALT.

The most common adverse reactions observed in greater than or equal to 20% of patients with CML who were resistant or intolerant to prior therapy were diarrhea, nausea, abdominal pain, rash, thrombocytopenia, vomiting, anemia, fatigue, pyrexia, cough, headache, ALT, and edema. The most common Grade 3/4 adverse reactions and laboratory abnormalities observed in greater than 10% of patients who were resistant or intolerant to prior therapy were thrombocytopenia, neutropenia, and anemia.

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

Proton Pump Inhibitors: Use 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.

Lactation: Because of the potential for serious adverse reactions in a nursing child, breastfeeding is not recommended during treatment with BOSULIF and for at least 1 month after the last dose.

Please see full U.S. Prescribing Information for BOSULIF here.

ABOUT ACUTE MYELOID LEUKEMIA (AML)

Acute myeloid leukemia is a rapidly progressing, life-threatening blood and bone marrow cancer. [1] If left untreated, patients with AML will die within months, if not weeks, of their disease. AML is the most common type of acute leukemia in adults and accounts for approximately 80% of all cases of acute leukemia.[2] About 1/33,000-1/25,000 people are expected to be newly diagnosed with AML in Europe annually.[2]

ABOUT CHRONIC MYELOGENOUS LEUKEMIA (CML)

Chronic myelogenous leukemia (CML) is a rare blood cancer, which begins in the bone marrow, but often moves into the blood.[3] Researchers estimate that by 2020, more than 412,000 people worldwide will be diagnosed with leukemia (all types).[4] Across Europe, CML constitutes about 15% of all leukemia and occurs with an incidence of about 1-1.5/100,000.[5]

About MYLOTARG™ (gemtuzumab ozogamicin)

MYLOTARG is an antibody-drug conjugate (ADC) composed of the cytotoxic agent calicheamicin, attached to a monoclonal antibody (mAB) targeting CD33, an antigen expressed on the surface of myeloblasts in up to 90 percent of AML patients.[6,7,8] When MYLOTARG binds to the CD33 antigen on the cell surface it is absorbed into the cell and calicheamicin is released causing cell death.[7,8]

MYLOTARG was approved by the U.S. Food and Drug Administration in September 2017 for adults with newly diagnosed CD33-positive AML, and adults and children 2 years and older with relapsed or refractory CD33-positive AML. MYLOTARG was originally approved in 2000 at a higher dose under the FDA's accelerated approval program for use as a single agent in patients with CD33-positive AML who had experienced their first relapse and were 60 years or older and who were not considered candidates for other cytotoxic chemotherapy. In 2010, Pfizer voluntarily withdrew MYLOTARG in the U.S. after a confirmatory trial failed to show clinical benefit and there was a higher rate of fatal toxicity compared to chemotherapy. MYLOTARG has been available to individual patients through Pfizer's compassionate use programs.

In addition, MYLOTARG is commercially available in Japan where it has been approved since 2005 for the treatment of patients with relapsed or refractory CD33-positive AML who are not considered candidates for other cytotoxic chemotherapy.

MYLOTARG originates from a collaboration between Pfizer and Celltech, now UCB. Pfizer has sole responsibility for all manufacturing, clinical development and commercialization activities for this molecule.

Pfizer also collaborated with SFJ Pharmaceuticals Group on the registrational program for MYLOTARG.

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. In the U.S., BOSULIF (bosutinib) is indicated for the treatment of adult patients with newly-diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML). Continued approval for this indication may be contingent upon verification and confirmation of clinical benefit in an ongoing long-term follow up trial. BOSULIF is also indicated in the U.S for the treatment of adult patients with chronic, accelerated or blast phase Ph+ CML with resistance or intolerance to prior therapy (first approved in September 2012).

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.

About Pfizer Oncology

Pfizer Oncology is committed to pursuing innovative treatments that have a meaningful impact on people living with cancer. Our growing pipeline of biologics, small molecules, and immunotherapies is focused on identifying and translating the best scientific breakthroughs into clinical application for patients across a diverse array of solid tumors and hematologic cancers. Today, we have 10 approved oncology medicines and 17 assets currently in clinical development. By maximizing our internal scientific resources and collaborating with other companies, government and academic institutions, as well as non-profit and professional organizations, we are bringing together the brightest and most enterprising minds to take on the toughest cancers. Together we can accelerate breakthrough treatments to patients around the world and work to redefine life with cancer.

Pfizer Inc.: 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 @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of February 23, 2018. 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 Pfizer's oncology portfolio, MYLOTARG (gemtuzumab ozogamicin), an antibody-drug conjugate, and BOSULIF (bosutinib), a tyrosine kinase inhibitor, including potential indications in the EU and their potential benefits that involve 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 the ability to meet anticipated clinical 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; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when applications for MYLOTARG and BOSULIF may be filed in any other jurisdictions; whether and when the European Commission may approve the pending applications for MYLOTARG and BOSULIF in the EU and whether and when any such other applications for MYLOTARG and BOSULIF that may be pending or filed may be approved by regulatory authorities, 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; uncertainties regarding the commercial success of MYLOTARG and BOSULIF; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of MYLOTARG and BOSULIF; 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, 2017 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 U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

1 Orpha.net. The portal for rare diseases and orphan drugs. Accessed February 2018. http://www.orpha.net/consor4.01/www/cgi-bin/OC_Exp.php?lng=EN&Expert=519

2 Leukemia & Lymphoma Society, Acute Myeloid Leukemia Booklet. Developed 2011. Accessed February 2018. https://www.lls.org/sites/default/files/file_assets/aml.pdf

3 American Cancer Society. What is Chronic Myeloid Leukemia? http://www.cancer.org/acs/groups/cid/documents/webcontent/003112-pdf.pdf. Accessed February 2018.

4 GLOBOCAN Online Analysis/Prediction. http://globocan.iarc.fr/old/burden.asp?selection_pop=224900&Text-p=World&selection_cancer=12280&Text-c=Leukaemia&pYear=8&type=0&window=1&submit=%C2%A0Execute. Accessed February 2018.

5 European Treatment and Outcome Study. https://www.eutos.org/content/registry/index_eng.html. Accessed February 2018.

6 Griffin JD, Linch D, Sabbath K, et al: A monoclonal antibody reactive with normal and leukemic human myeloid progenitor cells. Leuk Res. 8: 521-534, 1984 CrossRefMedline.

7 Tanaka M, Kano Y, et al. The cytotoxic effects of gemtuzumab ozogamicin (Mylotarg) in combination with conventional antileukemic agents by isobologram Analysis In Vitro. Anticancer Research. 2009; 29: 4589-4596.

8 O'Hear C, Heiber JF, Schubert I, Fey G, Geiger TL. Anti-CD33 chimeric antigen receptor targeting of acute myeloid leukemia. Haematologica. 2015;100(3):336-344.

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