Pfizer Logo

MYLOTARG™ Approved In The EU For The Treatment Of Previously Untreated, De Novo, CD33-positive Acute Myeloid Leukemia In Combination With Chemotherapy

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Pfizer Inc. (NYSE:PFE) today announced that the European Commission has approved MYLOTARG™ (gemtuzumab ozogamicin) in combination with daunorubicin and cytarabine 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). MYLOTARG is the first and only AML therapy approved in the European Union (EU) that targets CD33, an antigen expressed on AML cells in up to 90% of patients.1,2,3

“The marketing authorization of MYLOTARG provides a much-needed treatment option offering renewed hope for many acute myeloid leukemia patients in Europe,” said Andreas Penk, M.D., regional president, Pfizer Oncology. “In clinical trials, the addition of MYLOTARG to standard chemotherapy resulted in deeper, more durable remission, thus providing an additional treatment option with the potential to prevent relapse for these patients.”

AML is a rapidly progressing, life-threatening blood and bone marrow cancer.4 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.5About 16,800 people are expected to be newly diagnosed with AML in Europe annually.6 The goal of AML treatment is for the patient to achieve a complete, prolonged remission. Longer periods of remission prior to relapse are associated with better long-term outcomes for patients. Thus, medicines that delay the time until the disease comes back and extend life can provide meaningful clinical benefit.

“I am thrilled that MYLOTARG will be available soon in Europe as a first-line treatment for patients with acute myeloid leukemia,” said Doctor Sylvie Castaigne, Professeur des Universités, Université de Versailles - Saint Quentin, Praticien Hospitalier, Centre Hospitalier de Versailles, and lead investigator of the ALFA-0701 study. “This important milestone is a result of close collaboration between Pfizer and clinical investigators around the world, particularly the ALFA investigators in France, who believed in the promise of this therapy. We thank all of the investigators, nurses and patients who participated in these studies.”

The European Commission’s approval of MYLOTARG was based on data from an investigator-led, Phase 3 randomized, open-label study (ALFA-0701) in previously untreated, de novo patients. MYLOTARG received approval by the U.S. Food and Drug Administration in September 2017 for adults with newly diagnosed CD33-positive acute myeloid leukemia (AML), and adults and children 2 years and older with relapsed or refractory CD33-positive AML.

Pfizer is advancing a broad range of therapies that leverage multiple pathways and mechanisms of action (MOAs) to address acute and chronic leukemias, myeloproliferative disorders and lymphomas. Pfizer currently has four marketed therapies for hematologic cancers worldwide as well as several therapies in clinical development. Pfizer is also forging collaborations with a diversity of industry, academic and community partners to study multiple paths to advancing treatment. By working together, Pfizer and its partners aim to overcome the challenges of hematologic cancers and deliver meaningful benefits to patients.

Indication for MYLOTARG ™ (gemtuzumab ozogamicin) in the EU

MYLOTARG is approved in combination with daunorubicin and cytarabine for the treatment of patients age 15 and above with previously untreated, de novo, CD33-positive acute myeloid leukemia (AML), except acute promyelocytic leukemia (APL).

IMPORTANT MYLOTARG™ (gemtuzumab ozogamicin) SAFETY INFORMATION in the EU

The overall safety profile of MYLOTARG is based on data from patients with acute myeloid leukemia from the combination therapy study ALFA-0701, monotherapy studies, and from post-marketing experience.

Hepatotoxicity, including life-threatening, and sometimes fatal hepatic failure and VOD/SOS have been reported in patients treated with MYLOTARG. Other special warnings and precautions include myelosuppression and infusion-related reactions.

In the combination therapy study ALFA-0701, clinically relevant serious adverse reactions were hepatotoxicity, including VOD/SOS (3.8%), hemorrhage (9.9%), severe infection (41.2%), and tumour lysis syndrome (1.5%). In monotherapy studies, clinically relevant serious adverse reactions also included infusion related reactions (2.5%), thrombocytopenia (21.7%), and neutropenia (34.3%).

The most common adverse reactions (> 30%) in the combination therapy study were hemorrhage and infection. In monotherapy studies the most common adverse reactions (> 30%) included pyrexia, nausea, infection, chills, hemorrhage, vomiting, thrombocytopenia, fatigue, headache, stomatitis, diarrhea, abdominal pain, and neutropenia.

The most frequent (? 1%) adverse reactions that led to permanent discontinuation in the combination therapy study were thrombocytopenia, VOD, hemorrhage and infection. The most frequent (? 1%) adverse reactions that led to permanent discontinuation in monotherapy studies were infection, hemorrhage, multi-organ failure, and VOD.

The EU Summary of Product Characteristics (SmPC) will be available at http://www.ema.europa.eu.

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.1,2,3When MYLOTARG binds to the CD33 antigen on the cell surface it is absorbed into the cell and calicheamicin is released causing cell death.2,3

MYLOTARG was approved by the U.S. Food and Drug Administration in September 2017 for adults with newly diagnosed CD33-positive acute myeloid leukemia (AML), and adults and children 2 years and older with relapsed or refractory CD33-positive AML.

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 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 April 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 MYLOTARG (gemtuzumab ozogamicin), an antibody-drug conjugate, and Pfizer's oncology portfolio, including 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, uncertainties regarding the commercial success of MYLOTARG; 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; whether and when applications for MYLOTARG may be filed in any other jurisdictions and whether and when applications for any other oncology products may be filed in any jurisdictions; whether and when any such applications for MYLOTARG or any such other oncology products 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, and, if approved, whether such products will be commercially successful; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of MYLOTARG or any such other oncology products; 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.

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1 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.

2 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.

3 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.

4 Orpha.net. The portal for rare diseases and orphan drugs. Accessed December 2017. http://www.orpha.net/consor4.01/www/cgi-bin/OC_Exp.php?lng=EN&Expert=519

5 Leukemia & Lymphoma Society, Acute Myeloid Leukemia Booklet. Developed 2011. Accessed July 2017. https://www.lls.org/sites/default/files/file_assets/aml.pdf

6 RARECARE. Surveillance of rare cancers in Europe. Available at: http://dcnapp4.dcn.ed.ac.uk/rcnet/searchpage.aspx. Accessed March 14, 2018.

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