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FDA Advisory Committee Votes in Favor of Pfizer's MYLOTARG (gemtuzumab ozogamicin) for Acute Myeloid Leukemia

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Committee votes 6-1 that MYLOTARG in combination with chemotherapy has a favorable risk:benefit profile for patients with newly-diagnosed CD33-positive AML

Pfizer Inc. (NYSE:PFE) today announced that the U.S. Food and Drug Administration's (FDA) Oncologic Drug Advisory Committee (ODAC) voted that the results of ALFA-0701 demonstrated a favorable risk:benefit profile for MYLOTARG (gemtuzumab ozogamicin) 3 mg/m2 on days 1, 4 and 7 added to chemotherapy for patients with newly-diagnosed CD33-positive acute myeloid leukemia (AML). The role of the Advisory Committee is to provide recommendations to the FDA. The FDA decision on whether or not to approve the MYLOTARG application is anticipated by September 2017.

"We are extremely pleased with the Committee's recommendation and believe this is an important step toward our goal of making MYLOTARG available to patients with newly-diagnosed AML," said Mace Rothenberg, MD, Chief Development Officer, Oncology, Pfizer Global Product Development. "We look forward to working closely with the FDA as we continue the regulatory process. We are grateful to both the investigators who led MYLOTARG clinical trials and the patients who participated."

The ODAC discussions were based on the Biologics License Application (BLA) currently under review by the FDA. The BLA includes Pfizer-sponsored studies from the original New Drug Application (NDA) for MYLOTARG, an investigator-led Phase 3 randomized, open-label study (ALFA-0701) and an individual patient data meta-analysis from over 3,000 patients in five randomized Phase 3 studies (including ALFA-0701). These studies span 10 years of research and include more than 4,300 patients.

"Clinical studies investigating MYLOTARG have provided a significant body of evidence supporting the risk:benefit profile of MYLOTARG in AML," said Jorge Cortes, MD, University of Texas, MD Anderson Cancer Center. "Based on the totality of the efficacy and safety data, MYLOTARG, if approved, has the potential to be an important treatment option for adult patients with AML."

Due to the critical unmet need for patients with newly-diagnosed AML, there has been great interest among AML investigators to evaluate MYLOTARG in this population using different doses and different schedules of MYLOTARG. These investigator-led clinical trials have provided more information on the efficacy and safety of MYLOTARG.

ODAC is an independent panel of experts that evaluates data concerning the efficacy and safety of marketed and investigational cancer treatments and makes recommendations to the FDA. Its vote is not binding, but is

considered by the FDA in its decision-making process.

About AML

Acute myeloid leukemia (AML) is the most common type of acute leukemia in adults and accounts for approximately 80% of all cases of acute leukemia.1 About 21,380 people are expected to be diagnosed with AML in the United States in 2017.2 Despite recent developments in understanding the scientific basis of AML and its treatment, there has been little progress in increasing the long-term survival rate in AML patients.3 Only one in four patients with AML survive longer than five years.2

About MYLOTARG (gemtuzumab ozogamicin)

MYLOTARG is an investigational antibody-drug conjugate (ADC) comprised of the cytotoxic agent calicheamicin, attached to a monoclonal antibody (mAB) targeting CD33, an antigen expressed on the surface of myeloblasts in more than 90 percent of AML patients.4,5,6 When MYLOTARG binds to the CD33 antigen on the cell surface it is absorbed into the cell and calicheamicin is released causing cell death.4,5

MYLOTARG was originally approved under the FDA's accelerated approval program in 2000 for use as a single agent in patients with CD33-positive AML who had experienced their first relapse and were 60 years or older. In 2010, Pfizer voluntarily withdrew MYLOTARG after a confirmatory Phase 3 trial (SWOG S0106) did not show a clinical benefit, and the rate of fatalities as a result of treatment-related toxicity was significantly higher in the MYLOTARG arm.

While ODAC discussed MYLOTARG for newly-diagnosed CD33-positive AML, Pfizer is currently seeking approval in the U.S. for MYLOTARG in two indications:

- In combination with standard chemotherapy for the treatment of previously untreated de novo CD33-positive AML.
- As monotherapy for the treatment of CD33-positive AML patients in first relapse who are 60 years of age or older and who are not considered candidates for other cytotoxic chemotherapy.

MYLOTARG is commercially available in Japan where it is approved 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 and clinical development activities for this molecule.

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, one of the most robust in the industry, 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.

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 current as of July 11, 2017. 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, an antibody-drug conjugate, including 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 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; whether and when the BLA or any other such applications for MYLOTARG may be approved by the FDA or other regulatory authorities, respectively, 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 MYLOTARG; 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 U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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1 Leukemia & Lymphoma Society, Acute Myeloid Leukemia Booklet. Developed 2011. Accessed April 13, 2017. https://www.lls.org/sites/default/files/file_assets/aml.pdf

2 SEER Cancer Stat Facts: Acute Myeloid Leukemia. National Cancer Institute. Bethesda, MD, April 2017. Available at: http://seer.cancer.gov/statfacts/html/amyl.html. Accessed April 28, 2017.

3 National Cancer Institute. Cancer Stat Facts: Acute Myeloid Leukemia. Available at https://seer.cancer.gov/statfacts/html/amyl.html. Accessed on April 26, 2017.

4 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.

5 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.

6 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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