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Pfizer Receives Positive CHMP Opinion for BESPONSA® (Inotuzumab Ozogamicin) for the Treatment of Relapsed or Refractory Acute Lymphoblastic Leukemia

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Pfizer Inc. (NYSE:PFE) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending approval of BESPONSA®(inotuzumab ozogamicin) in the European Union (EU) as monotherapy for the treatment of adults with relapsed or refractory CD22-positive B-cell precursor Philadelphia chromosome negative (Ph-) acute lymphoblastic leukemia (ALL) and Philadelphia chromosome positive (Ph+) ALL, who have previously failed treatment with at least one tyrosine kinase inhibitor (TKI). The CHMP's opinion will now be reviewed by the European Commission (EC). If approved, BESPONSA will be the first antibody drug conjugate available for patients with this type of leukemia.

"Relapsed or refractory ALL is a rapidly progressive and often fatal disease. BESPONSA is an antibody-drug conjugate that has been designed to bind to a receptor – CD22 – that is present on the leukemia cells of most patients with ALL and deliver a potent toxin – calicheamicin – into those cells," said Mace Rothenberg, MD, chief development officer, Oncology, Pfizer Global Product Development. "The positive results of the INO-VATE 1022 Phase 3 trial provide strong evidence of the important role BESPONSA may have versus commonly used chemotherapy regimens used in this situation, and we believe BESPONSA could provide patients with relapsed or refractory ALL with a much needed treatment option."

"Approximately 10,000 new adult cases of ALL are diagnosed in Europe each year, and there is an urgent unmet need for patients with relapsed or refractory adult ALL, as the reported long term survival rates range from between less than 10 percent to approximately 20 percent1," said Professor Matthias Stelljes, Department of Medicine A/Hematology and Oncology, University of Münster, Germany. "Today's decision by the CHMP to recommend marketing authorization of BESPONSA is an important step forward for patients in Europe, and the community looks forward to potentially having a new treatment option available."

ALL is an aggressive type of leukemia with a poor prognosis in adults.2 The current foundational treatment is intensive, long-term chemotherapy.3 ALL is uncommon in adults, representing about 15 percent of leukemias, with about 10,000 new adult cases diagnosed in Europe each year.4 Approximately 20 to 40 percent of newly diagnosed adults with ALL are cured with current treatment regimens,5 however about 20 percent of adult patients will be refractory, or resistant, to treatment, and an additional 40 to 50 percent will relapse within months or years. For patients with relapsed or refractory adult ALL, the five-year overall survival rate is less than 10 percent.6

The Marketing Authorization Application (MAA) for BESPONSA was based on results from the Phase 3 INO-VATE 1022 trial, which enrolled 326 adult patients with relapsed or refractory B-cell ALL, and compared

BESPONSA to standard of care chemotherapy. The INO-VATE 1022 study had two primary endpoints, complete response with or without hematologic remission (CR/CRi) and overall survival (OS). Results from the trial were published in *The New England Journal of Medicine* in June 2016.

A Biologics License Application (BLA) for BESPONSA for the treatment of adult patients with relapsed or refractory B-cell precursor ALL has been accepted for filing and granted Priority Review by the U.S. Food and Drug Administration (FDA). The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA is in August 2017. BESPONSA received Breakthrough Therapy designation from the FDA in October 2015 for ALL.

With a growing hematology pipeline, Pfizer is committed to extending therapeutic progress in acute and chronic leukemias that leverage select pathways and mechanism of actions (MOAs). Specifically, our investigational products aim to treat some of the hardest to treat leukemias, including acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL), chronic myeloid leukemia (CML) and mantle cell lymphoma (MCL).

About BESPONSA® (Inotuzumab Ozogamicin)

BESPONSA is an investigational antibody-drug conjugate (ADC) comprised of a monoclonal antibody (mAb) targeting CD22, a cell surface antigen found on cancer cells in almost all B-ALL patients, linked to a cytotoxic agent.7 When BESPONSA binds to the CD22 antigen on B-cells, it is internalized into the cell, where the cytotoxic agent, calicheamicin, is released to destroy the cell.8 The most common adverse events (AEs) observed in clinical trials for BESPONSA were cytopenias, including febrile neutropenia. Common nonhematologic treatment-emergent AEs with BESPONSA included nausea, headache and pyrexia. Additionally, veno-occlusive liver disease (VOD) was observed more frequently in patients treated with BESPONSA, especially those who went on to receive hematopoietic stem cell transplantation.

BESPONSA 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 healthcare products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer healthcare 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, Pfizer has 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 21, 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 BESPONSA (inotuzumab ozogamicin), an investigational oncology therapy, 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, without limitation, 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 BESPONSA may be filed in any other jurisdictions; whether and when the MAA, the BLA and any such other applications for BESPONSA may be approved by the European Commission, 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 BESPONSA; 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, 2016 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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