Pfizer Announces Acceptance of Regulatory Submission for Inotuzumab Ozogamicin by the U.S. Food and Drug Administration

Tuesday, February 21, 2017 - 03:00am

Application Requests Approval for the Treatment of Relapsed or Refractory Acute Lymphoblastic Leukemia in Adults

“Based on the positive results of the INO-VATE 1022 Phase 3 trial, we believe inotuzumab ozogamicin, if approved, represents a new treatment option for adult patients with relapsed or refractory B-cell precursor ALL.”

Pfizer Inc. (NYSE:PFE) today announced that a Biologics License Application (BLA) for inotuzumab ozogamicin has been accepted for filing and granted Priority Review by the U.S. Food and Drug Administration (FDA). Inotuzumab ozogamicin is being evaluated for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

Inotuzumab ozogamicin received Breakthrough Therapy designation from the FDA in October 2015 for ALL. Priority Review status accelerates FDA review time from 10 months to a goal of six months from the day of acceptance of filing, and is given to drugs that may offer major advances in treatment or may provide a treatment for which no adequate therapy exists. The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA is in August 2017.

“ALL that has recurred after, or is refractory to, first-line therapy is a rapidly progressing and deadly disease,” said Mace Rothenberg, MD, chief development officer, Oncology, Pfizer Global Product Development. “Based on the positive results of the INO-VATE 1022

Phase 3 trial, we believe inotuzumab ozogamicin, if approved, represents a new treatment option for adult patients with relapsed or refractory B-cell precursor ALL.”

In addition, a Marketing Authorization Application (MAA) for inotuzumab ozogamicin in the same patient population is currently under review by the European Medicines Agency (EMA).

The submissions are 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 inotuzumab ozogamicin to standard of care chemotherapy. The INO-VATE 1022 study had two independent 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.

About Acute Lymphoblastic Leukemia (ALL)

Acute lymphoblastic leukemia (ALL) is an aggressive type of leukemia with a poor prognosis in adults.1 The current foundational treatment is intensive, long-term chemotherapy.2 In 2017, it is estimated that 5,970 cases of ALL will be diagnosed in the United States, with about 2 in 5 cases occurring in adults.3 Approximately 20 to 40 percent of newly diagnosed adults with ALL are cured with current treatment regimens.4 For patients with relapsed or refractory adult ALL, the five-year overall survival rate is less than 10 percent.5

About Inotuzumab Ozogamicin

Inotuzumab ozogamicin is an investigational antibody-drug conjugate (ADC) comprised of a monoclonal antibody (mAb) targeting CD22, a cell surface antigen expressed on approximately 90 percent of B-cell malignancies, linked to a cytotoxic agent.6 When inotuzumab ozogamicin 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.7 The most common adverse events (AEs) observed in clinical trials for inotuzumab ozogamicin were cytopenias, including febrile neutropenia. Common nonhematologic treatment-emergent AEs with inotuzumab ozogamicin included nausea, headache and pyrexia. Additionally, veno-occlusive liver disease (VOD) was observed more frequently in patients treated with inotuzumab ozogamicin, especially those who went on to receive hematopoietic stem cell transplantation.

Inotuzumab ozogamicin 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. For more information, please visit us at www.pfizer.com. In addition, to learn more, 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 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 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 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 inotuzumab ozogamicin may be filed in any other jurisdictions; whether and when the BLA, MAA and any other such applications for inotuzumab ozogamicin may be approved by the FDA, the EMA 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 inotuzumab ozogamicin; 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.

1 National Cancer Institute: Adult Acute Lymphoblastic Leukemia Treatment (PDQ®) – General Information About Adult Acute Lymphoblastic Leukemia (ALL). Available at: http://www.cancer.gov/cancertopics/pdq/treatment/adultALL/HealthProfessional/page1. Accessed March 21, 2016. 2 American Cancer Society: Typical treatment of acute lymphocytic leukemia. Available at: http://www.cancer.org/cancer/leukemia-acutelymphocyticallinadults/detailedguide/leukemia-acute-lymphocytic-treating-typical-treatment. Accessed March 21, 2016.

3 American Cancer Society: What are the key statistics about acute lymphocytic leukemia? Available at:http://www.cancer.org/cancer/leukemia-acutelymphocyticallinadults/detailedguide/leukemia-acute-lymphocytic-key-statistics . Accessed January 26, 2017.

4 Manal Basyouni A. et al. Prognostic significance of survivin and tumor necrosis factor-alpha in adult acute lymphoblastic leukemia. doi:10.1016/j.clinbiochem.2011.08.1147.

5 Fielding A. et al. Outcome of 609 adults after relapse of acute lymphoblastic leukemia (ALL); an MRC UKALL12/ECOG 2993 study. Blood. 2006; 944-950.

6 Leonard J et al. Epratuzumab, a Humanized Anti-CD22 Antibody, in Aggressive Non-Hodgkin’s Lymphoma: a Phase I/II Clinical Trial Results. Clinical Cancer Research. 2004; 10: 5327-5334.

7 DiJoseph JF. Antitumor Efficacy of a Combination of CMC-544 (Inotuzumab Ozogamicin), a CD22-Targeted Cytotoxic Immunoconjugate of Calicheamicin, and Rituximab against Non-Hodgkin’s B-Cell Lymphoma. Clin Cancer Res. 2006; 12: 242-250.

Media: Sally Beatty, 212-733-6566 Investors: Ryan Crowe, 212-733-8160