Pfizer’s Inotuzumab Ozogamicin Receives FDA Breakthrough Therapy Designation for Acute Lymphoblastic Leukemia (ALL)

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Advancing therapies for patients with adult acute lymphoblastic leukemia is crucial as only 10 percent of adults with ALL who relapse after first-line therapy survive five years or more with current treatment options.

Pfizer Inc. today announced that investigational antibody-drug conjugate (ADC) inotuzumab ozogamicin received Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for acute lymphoblastic leukemia (ALL).

The Breakthrough Therapy designation was based on the results of the Phase 3 INO-VATE ALL trial, which enrolled 326 adult patients with relapsed or refractory CD22-positive ALL and compared inotuzumab ozogamicin to standard of care chemotherapy. Topline results from the trial were announced in April 2015 and also presented at the 20th Congress of the European Hematology Association (EHA).

“Inotuzumab ozogamicin is the third Pfizer oncology medicine to be granted Breakthrough Therapy designation by the FDA, underscoring our commitment to innovative research and development that addresses significant unmet needs. Breakthrough Therapy designation will allow us to work more closely with the FDA to bring this important therapy to patients as rapidly as possible,” said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs and chief medical officer for Pfizer Oncology. “Advancing therapies for patients with adult acute lymphoblastic leukemia is crucial as only 10 percent of adults with ALL who relapse after

first-line therapy survive five years or more with current treatment options."1

Enacted as part of the 2012 FDA Safety and Innovation Act (FDASIA), Breakthrough Therapy designation is intended to expedite the development and review of a potential new medicine if it is "intended to treat a serious or life-threatening disease and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies."2 The Breakthrough Therapy designation is distinct from the FDA's other mechanisms to expedite drug development and review.3

About Acute Lymphoblastic Leukemia (ALL)

Acute lymphoblastic leukemia (ALL) is an aggressive type of leukemia with high unmet need and a poor prognosis in adults.4The current standard treatment is intensive, long-term chemotherapy.5 In 2015, it is estimated that 6,250 cases of ALL will be diagnosed in the United States6, with about 1 in 3 cases in adults. Only approximately 20 to 40 percent of newly diagnosed adults with ALL are cured with current treatment regimens.7 For patients with relapsed or refractory adult ALL, the five-year overall survival rate is less than 10 percent.8

About Inotuzumab Ozogamicin

Inotuzumab ozogamicin is an investigational antibody-drug conjugate (ADC) comprised of a monoclonal antibody (mAb) targeting CD22,9 a cell surface antigen expressed on approximately 90 percent of B-cell malignancies,10 linked to a cytotoxic agent. When inotuzumab ozogamicin binds to the CD22 antigen on malignant B-cells, it is internalized into the cell, where the cytotoxic agent calicheamicin is released to destroy the cell.11

Inotuzumab ozogamicin 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.

About Pfizer Oncology

Pfizer Oncology is committed to the discovery, investigation and development of innovative treatment options to improve the outlook for cancer patients worldwide. Our strong pipeline of biologics and small molecules, 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 breakthrough medicines, to deliver the right drug for each patient at the right time. For more information, please visitwww.Pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of October 19, 2015. 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 a potential indication for inotuzumab ozogamicin, an investigational oncology therapy, for the treatment of patients with acute lymphoblastic leukemia (ALL), 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 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 and uncertainties regarding whether the overall survival (OS) endpoint of the INO-VATE ALL study will be met; whether and when new drug applications may be filed in any jurisdictions for inotuzumab ozogamicin; whether and when any such applications 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; 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, 2014 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 SEC and available at www.sec.gov and www.pfizer.com.

1 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.

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3 U.S. Food and Drug Administration Frequently Asked Questions: Breakthrough Therapies. Available at:http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA Accessed July 11, 2015.

4 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 July 11, 2015.

5 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 July 11, 2015.

6 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 February 18, 2015.

7 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.

8 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.

9 Clinicaltrials.gov. A Study of Inotuzumab Ozogamicin versus Investigator’s Choice of Chemotherapy in Patients with Relapsed or Refractory Acute Lymphoblastic Leukemia. Available at: http://www.clinicaltrials.gov/ct2/show/NCT01564784?term=inotuzumab&rank=7. Accessed July 11, 2015.

10 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.

11 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.

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