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Pfizer Phase 3 Study Of Inotuzumab Ozogamicin Meets Primary Endpoint In Adult Patients With Relapsed Or Refractory Acute Lymphoblastic Leukemia

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Pfizer today announced that the Phase 3 study investigating the treatment of inotuzumab ozogamicin met its first primary endpoint of demonstrating a higher complete hematologic remission rate in adult patients with relapsed or refractory CD22-positive acute lymphoblastic leukemia (ALL) compared to that achieved with standard of care chemotherapy.

The Phase 3 study has two primary endpoints, complete hematologic remission rate and overall survival. Pfizer is continuing the study to allow for the data on overall survival to mature.

“We are excited about the results of the INO-VATE ALL study especially since relapsed and refractory acute lymphoblastic leukemia is a particularly difficult disease to treat in adults. The top-line results show that inotuzumab ozogamicin has the potential to be an important new treatment option for patients with relapsed or refractory disease,” said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs and chief medical officer for Pfizer Oncology. “We look forward to discussing these data with the FDA and other regulatory authorities.”

No new or unexpected safety issues were identified. Efficacy and safety data from this study will be submitted for presentation at an upcoming medical meeting.

About the INO-VATE ALL Study

The INO-VATE ALL Study, also known as Study 1022, is an open-label, randomized, Phase 3 study evaluating the safety and efficacy of the investigational compound inotuzumab ozogamicin as compared with a defined set of chemotherapy choices in adult patients with relapsed or refractory CD22-positive acute lymphoblastic leukemia (ALL).

The two primary endpoints are hematologic remission, defined as a complete response with or without platelet and/or neutrophil recovery (CR/CRi), and overall survival. Secondary endpoints include progression-free survival, volume of distribution and systemic clearance for inotuzumab ozogamicin in serum, duration of response, rate of stem-cell transplantation, minimal residual disease, cytogenetics, safety and quality of life (European Organization for Research and Treatment of Cancer, Quality of Life Questionnaire, Core-30 and EuroQual-5D Health Questionnaire).1

Inotuzumab ozogamicin was administered intravenously once weekly for three weeks for a three to four week cycle up to six cycles. Chemotherapy options included fludarabine, cytarabine and G-CSF (FLAG); high dose

cytarabine (HIDAC); or cytarabine and mitoxantrone.2

There were 326 patients enrolled in the trial. Enrollment is now complete.

About Acute Lymphoblastic Leukemia (ALL)

Acute lymphoblastic leukemia (ALL) is an aggressive type of leukemia with a poor prognosis in adults.3 The current foundational treatment is intensive, long-term chemotherapy.4 Approximately 20 to 40 percent of newly diagnosed adults with ALL are cured with current treatment regimens.5 For patients with relapsed or refractory adult ALL, the five-year overall survival rate is less than 10 percent.6

About Inotuzumab Ozogamicin

Inotuzumab ozogamicin is an investigational antibody-drug conjugate (ADC) comprised of a monoclonal antibody (mAb) targeting CD22,7 a cell surface antigen expressed on approximately 90 percent of B-cell malignancies,8 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.9

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 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 visit www.Pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of April 21, 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 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 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 other primary 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 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 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 February 20, 2015.

2 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 February 17, 2015.

3 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 February 18, 2015.

4 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 February 18, 2015.

5 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.

6 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.

7 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 February 18, 2015.

8 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.

9 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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