

Pfizer Discontinues Phase 3 Study of Inotuzumab Ozogamicin in Relapsed or Refractory Aggressive Non-Hodgkin Lymphoma (NHL) Due to Futility

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Pfizer to Continue Evaluation of Inotuzumab Ozogamicin in Other Hematologic Malignancies

"Hematologic cancers are a complex group of diseases, with more than 70 different types of lymphomas, leukemias or myelomas that require unique treatment options. We remain committed to evaluating inotuzumab ozogamicin in patients with hematologic malignancies."

[\(BUSINESS WIRE\)](#)--Pfizer Inc. announced today the discontinuation of a Phase 3 randomized, open-label, two-arm study (B1931008) evaluating the safety and efficacy of the investigational compound inotuzumab ozogamicin in patients with relapsed or refractory CD22+ aggressive non-Hodgkin lymphoma (NHL) who are not candidates for intensive high-dose chemotherapy. In this study, inotuzumab ozogamicin was administered on a once-a-month schedule in combination with rituximab and compared with an active comparator arm (investigator's choice of bendamustine plus rituximab or gemcitabine plus rituximab). During a scheduled interim analysis, an independent Data Monitoring Committee (DMC) concluded that in this study treatment with inotuzumab ozogamicin plus rituximab would not meet the primary objective of improving overall survival (OS) when compared to the comparator arm. No new or unexpected safety issues were identified.

"We are working to better understand the findings from this review to determine if there are any patterns of outcome that may help us gain greater understanding of the potential effect of inotuzumab ozogamicin in specific patient subsets within the heterogeneous patient population enrolled in this trial," said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs for Pfizer's Oncology Business Unit. "Hematologic cancers are a complex group of diseases, with more than 70 different types of lymphomas, leukemias or myelomas that require unique treatment options. We remain committed to evaluating inotuzumab ozogamicin in patients with hematologic malignancies."

Pfizer has notified the study investigators and appropriate regulatory authorities of the decision to discontinue the study. Investigators will work with patients in the study on an individual basis to determine an appropriate course of action.

Inotuzumab ozogamicin, administered on a weekly basis, 3 weeks out of 4, continues to be evaluated in adult acute lymphoblastic leukemia (ALL). The INO-VATE ALL Study (B1931022) is an open-label, randomized, Phase 3 study of inotuzumab ozogamicin compared to a defined investigator's choice of chemotherapy in adult patients with relapsed or refractory CD22+ ALL.

About Non-Hodgkin Lymphoma (NHL)

Non-Hodgkin lymphoma (NHL) is one of the most commonly occurring hematologic cancers among adults.¹ In 2008, there were approximately 355,900 new cases of NHL worldwide, and approximately 191,400 related deaths.² Indolent lymphomas, such as follicular lymphoma, show a high level of relapse, as treatment with chemotherapy alone has not yet resulted in an improvement in OS.³ Similarly, in aggressive disease, standard of care treatment achieves long-term remission in less than half of NHL cases, demonstrating an unmet need for both newly diagnosed and relapsed patients.⁴

About Acute Lymphoblastic Leukemia (ALL)

Acute lymphoblastic leukemia (ALL) is one of the four main types of leukemia. ALL is an aggressive type of leukemia; without treatment, most patients with acute leukemia would live only a few months.⁵ Of the estimated 48,610 new cases of all kinds of leukemia that will be diagnosed in the U.S. in 2013,⁶ about 6,070 cases will be diagnosed as ALL, of which about one out of three cases are in adults.⁵ The five-year relative survival rate of ALL overall (including adults and children) for 2003 – 2009 was approximately 66 percent.⁷ Survival rates in adults only are less favorable, with a five-year survival rate of less than 10 percent in this patient population.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 responsibility for all manufacturing and 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.

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DISCLOSURE NOTICE: The information contained in this release is as of May 20, 2013. 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.

Such risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for any potential indication for inotuzumab ozogamicin

as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; 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, 2012 and in its reports on Form 10-Q and Form 8-K.

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¹ Cheson B et al. Monoclonal Antibody Therapy for B-Cell Non-Hodgkin's Lymphoma. *New England Journal of Medicine*. 2008; 359: 613-626.

² American Cancer Society. Global Cancer Facts and Figures; 2nd Edition 2008. Available at: <http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-027766.pdf>.

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³ Van Oers MHJ. Rituximab maintenance improves clinical outcomes of relapsed/resistant follicular non-Hodgkin lymphoma in patients both with and without rituximab during induction: results of a prospective randomized phase 3 intergroup trial. *Blood*. 2006; 108: 3295-3301.

⁴ Hagemeister FB. Maintenance and Consolidation Strategies in Non-Hodgkin's Lymphoma: A Review of the Data. *Current Oncology Reports*. 2010; 1-7.

⁵ American Cancer Society: Detailed Guide – Acute Lymphocytic Leukemia. Available at: <http://www.cancer.org/acs/groups/cid/documents/webcontent/003109-pdf.pdf>. Accessed April 22, 2013.

⁶ National Cancer Institute. Surveillance Epidemiology and End Results Stat Fact Sheets: Leukemia. Available here: <http://seer.cancer.gov/statfacts/html/leuks.html>. Accessed May 2, 2013.

⁷ National Cancer Institute: SEER Stat Fact Sheets: Acute Lymphocytic Leukemia. Available at: <http://seer.cancer.gov/statfacts/html/aly1.html>. Accessed April 22, 2013.

⁸ Fielding A. et al. Outcome of 609 adults after relapse of acute lymphoblastic leukemia (ALL); an MRC UKALL12/ECOG 2003 study. *Blood*. 2006; 944-950.

⁹ Boni J et al. Modeling the Pharmacokinetic/Pharmacodynamic Platelet Response of Inotuzumab Ozogamicin, a Novel Antibody Drug Conjugate, Administered Alone or in Combination with Rituximab in Patients with Non-Hodgkin's Lymphoma. Accepted Poster Presentation at the European Society of Medical Oncology 2010 Annual Meeting, October 8-12, 2010. Milan, Italy.

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.

Pfizer Inc. Media: Victoria Davis, 484-865-5194 or Investors: Suzanne Harnett, 212-733-8009