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Pfizer To Present Clinical Data From Its Hematology Portfolio At The 53rd Annual Meeting Of The American Society Of Hematology

Monday, November 07, 2011 - 03:30am

Data to be Presented on Late-Stage Development Assets Bosutinib, Inotuzumab as Well as Early Phase Smoothened Inhibitor, PF-04449913 Investigator Research on Several Pfizer Compounds to be Presented Including an ASH Plenary Presentation on Gemtuzumab Ozogamicin

"Pfizer is committed to the evaluation and development of innovative therapies for hematologic malignancies,"

(BUSINESS WIRE)--Pfizer Oncology will present data on a number of investigational compounds from its hematology portfolio, including new data from bosutinib in chronic myeloid leukemia (CML),[1] inotuzumab in non-Hodgkin lymphoma (NHL),[2] as well as the first presentation of clinical data for PF-04449913,[3] which inhibits Smoothened (SMO), a key component of the Hedgehog pathway.[4] In addition, ongoing investigator-initiated research on gemtuzumab ozogamicin (Mylotarg) will be presented in the plenary session.[5] These data will be presented at the upcoming 53rd Annual Meeting of the American Society of Hematology (ASH) in San Diego, December 10-13.

“Pfizer is committed to the evaluation and development of innovative therapies for hematologic malignancies,” said Dr. Mace Rothenberg, senior vice president of clinical development and medical affairs for Pfizer’s Oncology Business Unit. “In addition to important results from company-initiated trials, we also support investigator-initiated research of compounds within our portfolio. The positive data to be presented at this meeting on gemtuzumab ozogamicin add to our understanding of this compound and the potential role of antibody-drug conjugates in hematologic malignancies. We are working closely with investigators to better understand the findings from this study and will work with regulatory authorities to determine next steps, as appropriate.”

Advancing a Robust Late-Stage Portfolio: Bosutinib and Inotuzumab

Key investigational compounds bosutinib and inotuzumab, both with ongoing Phase 3 trials,[6,7] will be featured in presentations at the upcoming meeting.[1,2]

Analyses of data evaluating bosutinib, an investigational oral dual Src and Abl kinase inhibitor,[1] as a single-agent in both newly diagnosed and previously treated patients with CML will be presented,[1,8] including:

- Bosutinib Versus Imatinib in Newly Diagnosed Chronic Phase Chronic Myeloid Leukemia – BELA Trial: 24-month Follow-up (Oral presentation, Abstract #455, December 12)[1]
- Activity of Bosutinib by Baseline and Emergent Mutation Status in Philadelphia Chromosome–Positive Leukemia Patients with Resistance or Intolerance to Other Tyrosine Kinase Inhibitors (Study 200) (Oral

presentation, Abstract #110, December 11)[8]
- In addition, multiple poster presentations for bosutinib in newly diagnosed and previously treated patients with CML have been accepted for presentation.[9,10,11]

Additionally, Phase 1 and 2 data will be presented on inotuzumab,[12,2] 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. [13,14] Inotuzumab is currently being evaluated in a Phase 3 study in combination with rituximab in patients with relapsed or refractory CD22-positive aggressive NHL who are not candidates for intensive high-dose chemotherapy.[7]

- Anti-CD22 Immunoconjugate Inotuzumab Ozogamicin + Rituximab Followed by Stem Cell Transplantation in Relapsed/Refractory DLBCL Patients: Safety and Efficacy (Study 2005) (Poster, Abstract #2718, December 11)[2]
- An Open-label, Phase I Study of R-CVP in Combination with Inotuzumab Ozogamicin in Patients with Relapsed/Refractory CD22-positive B-cell Non-Hodgkin Lymphoma (Study 1105) (Poster, Abstract #3715, December 12)[12]

New Pathways, New Promise in the Early-Stage Pipeline

For the first time, Pfizer will present clinical data for PF-04449913, an oral inhibitor of SMO,[3] one of the key components of the Hedgehog signaling pathway.[4] The study evaluates the effectiveness of PF-04449913 across multiple hematologic cancers, including CML, acute myeloid leukemia (AML), myelodysplatic syndrome, and myelofibrosis.[3]

- Phase 1 Dose-escalation Study of PF-04449913, an Oral Hedgehog Inhibitor, in Patients with Select Hematologic Malignancies (Oral presentation, Abstract #424, December 12)[3]

Abnormal activation of the Hedgehog pathway has been linked to multiple human cancers.[15] Recent data suggest that disruption of the hedgehog pathway or inhibition of its activity may provide a new strategy for the treatment of hematologic disorders, including multiple myeloma, lymphoma, and myeloid malignancies.[4,16]

Partnering to Gain a Better Understanding of our Cancer Therapies

Data on a range of investigator-initiated research will also be presented, including data on gemtuzumab ozogamicin to be featured in the Plenary Scientific Session:[5]

- Fractionated doses of Gemtuzumab Ozogamicin combined to standard chemotherapy improve event-free and overall survival in newly diagnosed *de novo* AML patients aged 50-70 years old: A prospective randomized Phase 3 trial from the Acute Leukemia French Association (ALFA) (Sylvie Castaigne, Hôpital André Mignot; Plenary presentation, Abstract #6, December 11)[5]

Background on Mylotarg®

In October 2010, Pfizer voluntarily withdrew the new drug application (NDA) for Mylotarg® (Gemtuzumab Ozogamicin for Injection) for the treatment of relapsed AML.[17] The required post-approval study (SWOG S0106) combining chemotherapy and Mylotarg given 6 mg/m2 for induction and then as monotherapy in doses of 5 mg/m2 (up to three doses given 28 days apart) for post-consolidation did not demonstrate improved survival compared with chemotherapy alone in patients aged 18-60 with previously untreated AML. Additionally, among all patients evaluable for early toxicity the fatal induction toxicity rate was significantly higher in patients given the combination of conventional induction chemotherapy and Mylotarg than in those treated with chemotherapy

alone.[18]

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, 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. Pfizer Oncology has biologics and small molecules in clinical development and more than 100 clinical trials underway. 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 November 7, 2011. 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 Pfizer's oncology pipeline in general and about various oncology product candidates, including their potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that have been or may be filed for such oncology product candidates as well as the decisions of regulatory authorities regarding labeling and other matters that could affect their 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, 2010 and in its reports on Form 10-Q and Form 8-K.

[1] ASH Accepted Abstract # 455. Bosutinib Versus Imatinib in Newly Diagnosed Chronic Phase Chronic Myeloid Leukemia – BELA Trial: 24-month Follow-up. Oral Presentation, Monday December 12, 2011: 11:30am PDT. J. Cortes – Presenter. 53rd American Society of Hematology Annual Meeting. San Diego, CA. December 10-13, 2011.

[2] ASH Accepted Abstract # 2718. Anti-CD22 Immunoconjugate Inotuzumab Ozogamicin + Rituximab Followed by Stem Cell Transplantation in Relapsed/Refractory DLBCL Patients: Safety and Efficacy. General Poster Session, Sunday December 11, 2011: 6:00 – 8:00pm PDT. N. Wagner-Johnston – Presenter. 53rd American Society of Hematology Annual Meeting. San Diego, CA. December 10-13, 2011.

[3] ASH Accepted Abstract #424. Phase 1 Dose-escalation Study of PF-04449913, an Oral Hedgehog (Hh) Inhibitor, in Patients with Select Hematologic Malignancies. Oral Presentation, Monday December 12, 2011: 11:15am PDT. C. Jamieson – Presenter. 53rd American Society of Hematology Annual Meeting. San Diego, CA. December 10-13, 2011.

[4] Zhao C, Chen A, Jamieson CH et al. Hedgehog signalling is essential for maintenance of cancer stem cells in myeloid leukaemia. *Nature*. 2009.458:776-779.

[5] ASH Accepted Abstract #6. Fractionated doses of Gemtuzumab Ozogamicin (GO) combined to standard chemotherapy (CT) improve event-free and overall survival in newly-diagnosed de novo AML patients aged 50-70 years old: A prospective randomized Phase 3 trial from the Acute Leukemia French Association (ALFA). Plenary Presentation, Sunday December 11, 2011: 3:45 pm PDT. S. Castaigne – Presenter. 53rd American

Society of Hematology Annual Meeting. San Diego, CA. December 10-13, 2011.

[6] Clinicaltrials.gov. Compare Bosutinib to Imatinib in Subjects with Newly Diagnosed Chronic Phase Philadelphia Chromosome Positive CML. Available at: http://www.clinicaltrials.gov/ct2/show/NCT00574873?term=bosutinib&phase=2&rank=1. Accessed November 3, 2011.

[7] Clinicaltrials.gov. A Study of Inotuzumab Ozogamicin Plus Rituximab For Relapsed/Refractory Aggressive Non-Hodgkin Lymphoma Patients Who are Not Candidates for Intensive High-Dose Chemotherapy. Available at: http://www.clinicaltrials.gov/ct2/show/NCT01232556?term=inotuzumab+ozogamicin&phase=2&rank=2. Accessed November 3, 2011.

[8] ASH Accepted Abstract # 110. Activity of Bosutinib by Baseline and Emergent Mutation Status in Philadelphia Chromosome–Positive Leukemia Patients with Resistance or Intolerance to Other Tyrosine Kinase Inhibitors. Oral Presentation, Sunday December 11, 2011: 4:45pm PDT. H. J. Khoury – Presenter. 53rd American Society of Hematology Annual Meeting. San Diego, CA. December 10-13, 2011.

[9] ASH Accepted Abstract #1685. Safety and Management of Toxicities in the BELA Trial of Bosutinib Versus Imatinib in Newly Diagnosed Chronic Phase Chronic Myeloid Leukemia. General Poster Session, Saturday December 10, 2011: 5:30 – 7:30 pm PDT. C. Gambacorti-Passerini – Presenter. 53rd American Society of Hematology Annual Meeting. San Diego, CA. December 10-13, 2011.

[10] ASH Accepted Abstract #2760. Bosutinib Safety Profile and Management of Toxicities in Leukemia Patients with Resistance or Intolerance to Imatinib and Other Tyrosine Kinase Inhibitors. General Poster Session, Sunday December 11, 2011: 6:00 – 8:00 pm PDT. H. Kantarjian – Presenter. 53rd American Society of Hematology Annual Meeting. San Diego, CA. December 10-13, 2011.

[11] ASH Accepted Abstract #2769. The Incidence of Bcr-Abl Mutations and Their Impact on Clinical Outcome in Newly Diagnosed Chronic Phase Chronic Myeloid Leukemia Patients Treated with Bosutinib versus Imatinib in the BELA Trial. General Poster Session, Sunday December 11, 2011: 6:00 – 8:00 pm PDT. D. Kim – Presenter. 53rd American Society of Hematology Annual Meeting. San Diego, CA. December 10-13, 2011.

[12] ASH Accepted Abstract #3715. An Open-label, Phase 1 Study of R-CVP in Combination with Inotuzumab Ozogamicin in Patients with CD22-positive B-Cell Non-Hodgkin's Lymphoma. General Poster Session, Monday December 12, 2011: 6:00 – 8:00 pm PDT. M. Ogura – Presenter. 53rd American Society of Hematology Annual Meeting. San Diego, CA. December 10-13, 2011.

[13] 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.

[14] 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.

[15] Kubo M, Nakamura M, Tasaki A et al. Hedgehog Signaling Pathway is a New Therapeutic Target for Patients with Breast Cancer. *Cancer Res*. 2004;64:6071-6074.

[16] Jiang J and Hui C-C. Hedgehog Signaling in Development and Cancer. *Developmental Cell*. 2008; 15:801-812.

[17] Pfizer Inc. Pfizer Prepares for Voluntary Withdrawal of U.S. New Drug Application and for Discontinuation of Commercial Availability of Mylotarg. Available at: http://www.prnewswire.com/news-releases/pfizer-prepares-for-voluntary-withdrawal-of-us-new-drug-application-and-for-discontinuation-of-commercial-availability-of-mylotarg-96821539.html. Accessed October 26, 2011.

[18] Petersdorf S et al. Preliminary Results of the Southwest Oncology Group Study S0106: An International Intergroup Phase 3 Randomized Trial Comparing the Addition of Gemtuzumab Ozogamicin to Standard Induction Therapy Versus Standard Induction Therapy Followed by a Second Randomization to Post-Consolidation Gemtuzumab Ozogamicin Versus No Additional Therapy for Previously Untreated Acute Myeloid Leukemia. ASH Accepted Presentation, Monday December 7, 2009. 51st American Society of Hematology Annual Meeting. New Orleans, LA. December 5-9, 2009.

Pfizer Media: Chris Loder 212-733-7897 (office) 347-453-8199 (cell) Investors: Chuck Triano, 212-733-3901 (office)