Pfizer to Present Data from Its Hematology Portfolio at the 52nd Annual Meeting of the American Society of Hematology

Sunday, November 28, 2010 - 04:30pm

Company to Present Phase 3 Data Studying Bosutinib in Chronic Myeloid Leukemia Pfizer to Initiate Phase 3 Study of Inotuzumab Ozogamicin in Combination with Rituximab in Patients with Relapsed or Refractory CD22-Positive Aggressive Non-Hodgkin Lymphoma in 2011

"We believe that the investigational agents in our portfolio have the potential to make a difference in the lives of patients with CML and NHL,"

(BUSINESS WIRE)--Pfizer (NYSE: PFE) said today that new data on investigational compounds in its hematology portfolio will be presented at the 52nd Annual Meeting of the American Society of Hematology (ASH) in Orlando, December 4-7. Key highlights include results from a Phase 3 study, called the BELA (Bosutinib Efficacy and safety in chronic myeloid LeukemiA) study, involving bosutinib for the treatment of newly diagnosed Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML).(1) The company will also present Phase 2 data from inotuzumab ozogamicin (CMC-544) for the treatment of B-cell Non-Hodgkin lymphoma (NHL).(2) These presentations underscore the company's commitment to advancing new treatments for patients living with various hematologic malignancies, which represent the second leading cause of cancer death.(3)

Pfizer also announced that it would initiate an open-label, randomized, Phase 3 study, Study B1931008, of inotuzumab ozogamicin administered in combination with rituximab compared to defined investigator's choice therapy in subjects with relapsed or refractory CD22-positive aggressive NHL who are not candidates for intensive high-dose

chemotherapy.(4) This study will be open and enrolling in early 2011.

"We believe that the investigational agents in our portfolio have the potential to make a difference in the lives of patients with CML and NHL," said Dr. Len Mattano, Vice President, Tumor Strategy Lead for Pfizer's Oncology Business Unit. "Pfizer is committed to improving outcomes for patients living with hematologic cancers where unmet needs exist and is proud of our progress toward meeting these goals."

Pfizer will present data on several key candidates from its hematologic portfolio at ASH. These include:

Bosutinib

Bosutinib is an investigational, oral dual Src and Abl kinase inhibitor.(1) It is believed that by dual inhibition of the Src and Abl tyrosine kinases, bosutinib may inhibit signaling in CML cells that allows the cells to grow, survive and reproduce.(5)

Presentations on bosutinib include:

-- Oral presentation, Abstract #208, December 6.

An ongoing, Phase 3 randomized, open-label study of bosutinib versus imatinib in newly diagnosed patients with chronic phase Ph+ CML.(1)

-- Oral presentation, Abstract #892, December 7.

Data from a cohort of a Phase 1/2 single-arm study (Study 200) of bosutinib in patients with chronic phase Ph+ CML, who have failed prior imatinib therapy and were resistant or intolerant to dasatinib or resistant to nilotinib. Study 200 is an ongoing Phase 1/2 study in patients with Ph+ CML being treated in the second and third-line setting.(6)

-- Poster presentation, Abstract #3434, December 6.

Data from a Phase 1/2 study (Study 200) of hematologic and cytogenetic response rates in patients with or without Bcr-Abl mutations.(7)

Inotuzumab Ozogamicin

Inotuzumab ozogamicin is an investigational antibody-targeted cytotoxic targeting CD22,(8) an antigen expressed in approximately 90 percent of B-cell malignancies.(9) Linking an antibody with a cytotoxic agent is designed to direct chemotherapy to selected

cancer cells expressing the CD22 antigen. This targeted delivery is intended to result in less toxicity compared to non-targeted systemic delivery of currently used cytotoxic chemotherapy.(10)

Presentations on inotuzumab ozogamicin include:

-- Oral presentation, Abstract #430, December 6.

Preliminary details of Study 2001, a Phase 2 safety and efficacy study evaluating inotuzumab ozogamicin (CMC-544) in patients with indolent B-cell NHL, the most common type of NHL, that are relapsed or refractory to rituximab alone, rituximab in combination with chemotherapy or radioimmunotherapy (RIT) will be presented.(2)

-- Poster presentation, Abstract #2883, December 5.

Results from Study 2005, a Phase 2 safety and efficacy study of inotuzumab ozogamicin (CMC-544) plus rituximab followed by high dose therapy and autologous stem cell transplant (HDT-aSCT) in relapsed/refractory NHL patients including diffuse large B-cell lymphoma (DLBCL) patients.(11)

-- Poster presentation, Abstract #2872, December 5.

Safety, pharmacokinetics, and preliminary efficacy of inotuzumab ozogamicin (CMC-544) in combination with rituximab in Japanese patients with relapsed or refractory B-cell NHL.(8)

Additional Early Stage Data

Data on additional Pfizer compounds being studied in hematologic malignancies will also be presented:

-- Oral presentation, Abstract #860, December 6.

A Phase 1 trial evaluating PD 0332991 in combination with bortezomib or dexamethasone in relapsed or refractory multiple myeloma. PD 0332991 is a selective inhibitor of cyclin-dependent kinase (CDK) 4/6.(12)

-- Poster presentation, Abstract #2877, December 5.

Safety and activity of crizotinib (PF-02341066), an oral ALK inhibitor, in patients with ALK-positive anaplastic large cell lymphoma (ALCL) resistant to cytotoxic therapy.(13)

Crizotinib NSCLC Data Chosen for ASH/ASCO Joint Symposium

Pfizer will also present updated data as part of the ASH/ASCO Joint Symposium session from the Part 2 expanded cohort Phase 1 trial of crizotinib in patients with ALK-positive advanced non-small cell lung cancer (NSCLC) (December 5).(14) Crizotinib (PF-02341066) is a first-in-class compound that inhibits the anaplastic lymphoma kinase, or ALK,(15) and is representative of Pfizer's personalized medicine approach to cancer treatment. By inhibiting ALK, crizotinib (PF-02341066) blocks signaling in a number of cell pathways that may be critical for the growth and survival of tumor cells.(16) Crizotinib (PF-02341066) is also an inhibitor of c-MET (mesenchymal endothelial transition factor).(13)

These data will be presented at the 52nd Annual Meeting of the American Society of Hematology (ASH) in Orlando, December 4-7, 2010.

For Pfizer Oncology activities at ASH, visit Facebook (www.Facebook.com/Pfizer) and follow us on Twitter @pfizer_news (www.twitter.com/pfizer_news).

Pfizer's Commitment to Hematology

Pfizer Oncology is committed to developing therapies to treat a variety of hematologic malignancies in both adult and pediatric patient populations. Collectively, hematologic cancers represent the fifth most commonly occurring cancers and the second leading cause of cancer death.(2) While there have been significant advancements in the treatment of hematologic cancers, there continues to be a need for new therapeutic approaches, both for newly diagnosed patients and relapsed patients.(5,17) In order to deliver new options that target specific hematologic abnormalities and mutations, it is important to understand the molecular subtypes and genetic variations associated with hematologic cancers. Pfizer Oncology has biologics and small molecules in clinical development across a number of hematologic malignancies.

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, including breast, lung, prostate, sarcoma, melanoma, and various hematologic 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 29, 2010. 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 various oncology product candidates, including their potential benefits and potential advancement within the research and development pipeline, 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 may be filed for any such oncology product candidates as well as their decisions 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, 2009 and in its reports on Form 10-Q and Form 8-K.

1 ASH Accepted Abstract #208. An Ongoing Phase 3 Study of Bosutinib (SKI-606) Versus Imatinib In Patients with Newly Diagnosed Chronic Phase Chronic Myeloid Leukemia. Presenter – C. Gambacorti. 52nd American Society of Hematology Annual Meeting. December 4-7, 2010.

2 ASH Accepted Abstract #430. Inotuzumab Ozogamicin (CMC-544) In Patients with Indolent B-Cell NHL That Is Refractory to Rituximab Alone, Rituximab and Chemotherapy, or Radioimmunotherapy: Preliminary Safety and Efficacy From a Phase 2 Trial. Presenter – A Goy. 52nd American Society of Hematology Annual Meeting. December 4-7, 2010.

3 Mucke H. Hematological Cancer Therapeutics: Pipelines and Competition. Available at: http://www.insightpharmareports.com/reports/2005/53_BloodCancer/overview.asp. Accessed November 11, 2010.

4 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://clinicaltrials.gov/ct2/show/NCT01232556?term=inotuzumab+ozogamicin&phase=2&rank=
. Accessed November 8, 2010.

5 Konig H et al. Effects of Dasatinib on Src Kinase Activity and Downstream Intracellular Signaling in Primitive Chronic Myelogenous Leukemia Hematopoietic Cells. Cancer Research. 2008; 68: 9624-9633.

6 ASH Accepted Abstract #892. Bosutinib as Third-Line Treatment for Chronic Phase Chronic Myeloid Leukemia Following Failure of Second-Line Therapy with Dasatinib or Nilotinib. Presenter - H. J. Khoury. 52nd American Society of Hematology Annual Meeting. December 4-7, 2010.

7 ASH Accepted Abstract #3434. Clinical Activity of Bosutinib by Mutational Status In Patients with Previously Treated Philadelphia Chromosome–positive Leukemias. Presenter – C. Gambacorti. 52nd American Society of Hematology Annual Meeting. December 4-7, 2010.

8 ASH Accepted Abstract #2872. Phase 1 Study of Anti-CD22 Immunoconjugate Inotuzumab Ozogamicin (CMC-544) Plus Rituximab In Japanese Patients with Relapsed/Refractory B-Cell Non-Hodgkin Lymphoma. Presenter – K. Hatake. 52nd American Society of Hematology Annual Meeting. December 4-7, 2010.

9 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.

10 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.

11 ASH Accepted Abstract #2883. Anti-CD22 Immunoconjugate Inotuzumab Ozogamicin (CMC-544) + Rituximab In Relapsed DLBCL Patients Followed by Stem Cell Transplantation: Preliminary Safety and Efficacy. Presenter – N. Wagner-Johnston. 52nd American Society of Hematology Annual Meeting. December 4-7, 2010.

12 ASH Accepted Abstract #860. A Phase I Study of PD 0332991: Complete CDK4/6 Inhibition and Tumor Response In Sequential Combination with Bortezomib and Dexamethasone for Relapsed and Refractory Multiple Myeloma. Presenter – R. Niesvizky. 52nd American Society of Hematology Annual Meeting. December 4-7, 2010.

13 ASH Accepted Abstract #2877. Clinical Activity of Crizotinib In Advanced, Chemoresistant ALK+ Lymphoma Patients. Presenter – C. Gambacorti. 52nd American Society of Hematology Annual Meeting. December 4-7, 2010.

14 ASH/ASCO Joint Symposium: Clinical Activity of the Oral ALK Inhibitor, PF-02341066, In ALK Positive Patients with Non-Small Cell Lung Cancer (NSCLC). Presenter – E. Kwak. 52nd American Society of Hematology Annual Meeting. December 4-7, 2010.

15 ClinicalTrials.gov. A study of oral PF-02341066, A c-MET/Hepatocyte Growth Factor Tyrosine Kinase Inhibitor, in Patients with Advanced Cancer. Available at: http://clinicaltrials.gov/ct2/show/NCT00585195?term=A8081001&rank=1. Accessed August 31, 2010.

16 Bang Y et al. Clinical Activity of the Oral ALK Inhibitor, PF-02341066, in ALK Positive Patients with Non-Small Cell Lung Cancer (NSCLC). Accepted Plenary Presentation at the American Society of Clinical Oncology 2010 Annual Meeting, June 4-8, 2010.

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

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