Pfizer Logo

Pfizer to Present Clinical Data from Its Hematology Portfolio at the 54th Annual Meeting of the American Society of Hematology

Wednesday, November 28, 2012 - 09:30pm

Data to be presented on BOSULIF® (bosutinib) and Investigational Antibody Drug Conjugate, Inotuzumab Ozogamicin

"The data being presented on Pfizer compounds at ASH provide important new insights into marketed products like BOSULIF (bosutinib), agents in late-stage clinical development like inotuzumab ozogamicin, and our robust hematology pipeline. This is a reflection of Pfizer's strong commitment to bringing innovative therapies to patients with hematologic cancers,"

(BUSINESS WIRE)--Pfizer Oncology will present updated data in chronic myeloid leukemia (CML) for its oral Abl and Src kinase inhibitor, BOSULIF®(bosutinib),[1,2,3,4,5]recently approved by the U.S. Food and Drug Administration (FDA), and new data in acute lymphoblastic leukemia (ALL) and non-Hodgkin's lymphoma (NHL) for inotuzumab ozogamicin,[6,7]a CD-22 directed antibody drug conjugate (ADC) that is currently being studied in two Phase 3 trials (INO-VATE trials),[8,9]at the upcoming 54th Annual Meeting of the American Society of Hematology (ASH) in Atlanta, December 8-11.

"The data being presented on Pfizer compounds at ASH provide important new insights into marketed products like BOSULIF (bosutinib), agents in late-stage clinical development like inotuzumab ozogamicin, and our robust hematology pipeline. This is a reflection of Pfizer's strong commitment to bringing innovative therapies to patients with hematologic cancers," said Dr. Mace Rothenberg, senior vice president of clinical development and medical affairs for Pfizer's Oncology Business Unit.

BOSULIF (bosutinib) Tablets

BOSULIF, approved by the FDA in September 2012, is indicated for the treatment of adult patients with chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy. Once-daily BOSULIF was approved with pivotal trial data that included CML patients treated with imatinib followed by a second-generation tyrosine kinase inhibitor (TKI).

Despite advances made in recent years for the treatment of CML, additional therapeutic options are still needed for those patients who may never respond to initial treatment, may develop drug-resistant disease, or may not be able to tolerate their therapy.[3,4]

At ASH, Pfizer will present several analyses of Study 200, which evaluated BOSULIF in this patient population. Presentations include:

- Bosutinib as Therapy for Chronic Phase Chronic Myeloid Leukemia Following Resistance or Intolerance to Imatinib: 36-month Minimum Follow-up Update (Poster, Abstract #3779, December 10)[4]
- Bosutinib as Therapy for Chronic Phase Chronic Myeloid Leukemia Following Failure With Imatinib Plus Dasatinib and/or Nilotinib: 24-month Minimum Follow-up Update(Poster, Abstract #3785, December 10)[5]
- Baseline Predictors of Response to Bosutinib in Patients With Chronic Phase Chronic Myeloid Leukemia Following Resistance or Intolerance to Imatinib Plus Dasatinib and/or Nilotinib(Poster, Abstract #2793, December 9)[2]
- Assessment of Early Cytogenetic Response as a Predictor of Long-term Clinical Outcomes in a Phase 1/2 Study of Bosutinib in Chronic Phase CML (Poster, Abstract #2798, December 9)[3]

A secondary analysis from the Bosutinib Efficacy and safety in chronic myeloid Leukemia (BELA) study will be presented (Oral Presentation, Abstract #69, December 9).[1]

Inotuzumab Ozogamicin

Inotuzumab ozogamicin,[6,7]is an investigational ADC comprised of a monoclonal antibody (mAb) targeting CD22 that is linked to a cytotoxic agent.[10,11]Linking an ADC with a cytotoxic agent may allow chemotherapy to directly target the cancer cell[12,13] and maximize its antitumor effect while minimizing its normal tissue exposure, potentially resulting in an improved therapeutic index.[14]

At ASH, Pfizer will present analyses of Phase 1 data of inotuzumab ozogamicinin in the treatment of ALL and NHL:

- Weekly Inotuzumab Ozogamicin in Adult Patients with Relapsed or Refractory CD22-Positive Acute Lymphoblastic Leukemia (Poster, Abstract #2612, December 9)[7]
- 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: Preliminary Safety and Efficacy Data (Poster, Abstract #1633, December 8)[6]

Inotuzumab ozogamicin is currently being evaluated in two Phase 3 studies as part of the INO-VATE trials, which are currently open and enrolling new patients. The first is in combination with rituximab in adult patients with relapsed or refractory CD22-positive aggressive NHL who are not candidates for intensive high-dose chemotherapy.[8]The second study is in adult patients with relapsed or refractory CD22-positive ALL versus investigator's choice of chemotherapy.[9]

BOSULIF (bosutinib) Indication and Important Safety Information
BOSULIF is indicated for the treatment of adult patients with chronic, accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy.

Contraindication: Hypersensitivity to BOSULIF. Anaphylactic shock occurred in less than 0.2% of treated patients.

Gastrointestinal Toxicity: Diarrhea, nausea, vomiting, and abdominal pain can occur. In the clinical trial, median time to onset for diarrhea was 2 days, median duration was 1 day, and median number of episodes per patient was 3 (range 1-221). Monitor and manage patients using standards of care, including antidiarrheals, antiemetics, and/or fluid replacement. Withhold, dose reduce, or discontinue BOSULIF as necessary.

Myelosuppression: Thrombocytopenia, anemia, and neutropenia can occur. A complete blood count should be performed weekly for the first month and then monthly or as clinically indicated. Withhold, dose reduce, or discontinue BOSULIF as necessary.

Hepatic Toxicity: Twenty percent of patients experienced an increase in either alanine aminotransferase (ALT) or aspartate aminotransferase (AST). Liver-enzyme elevation usually occurs early in treatment. Perform monthly hepatic enzyme tests for the first 3 months and as clinically indicated. In patients with transaminase elevations, monitor liver enzymes more frequently. Drug-induced liver injury has occurred. Withhold, dose reduce, or discontinue BOSULIF as necessary.

Fluid Retention: Fluid retention can occur and may cause pericardial effusion, pleural effusion, pulmonary edema, and/or peripheral edema. Monitor and manage patients using standards of care. Interrupt, dose reduce, or discontinue BOSULIF as necessary.

Embryofetal Toxicity: BOSULIF may cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised of potential hazard to the fetus and to avoid becoming pregnant while receiving BOSULIF.

Adverse Reactions: The most common adverse reactions observed in greater than 20% of patients in the Phase 1/2 safety population (N=546) were diarrhea, nausea, thrombocytopenia, vomiting, abdominal pain, rash, anemia, pyrexia, and fatigue.

The most common Grade 3/4 adverse reactions and laboratory abnormalities observed in greater than 10% of patients were thrombocytopenia, anemia, and neutropenia.

Drug Interactions: Avoid concurrent use with strong or moderate CYP3A inhibitors or inducers.

Proton Pump Inhibitors: Consider using short-acting antacids or H2 blockers instead of PPIs. Separate antacid or H2 blocker dosing and BOSULIF dosing by more than 2 hours.

Substrates of P-glycoprotein: BOSULIF may increase the plasma concentrations of drugs that are P-gp substrates, such as digoxin.

Nursing Mothers: Given the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or BOSULIF.

Hepatic Impairment: Treat with a dose of 200 mg daily in patients with any baseline hepatic impairment.

For more information and full prescribing information, please visit www.BOSULIF.com.

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.

Hematologic cancers are a complex group of diseases, with over 70 different types of lymphomas, leukemias or myelomas. While there have been significant advancements in the treatment of some hematologic cancers, there continues to be a need for additional therapeutic options. Pfizer Oncology is committed to improving outcomes for patients living with hematologic malignancies like CML. Pfizer Oncology has a robust hematology pipeline, with biologics and small molecules in clinical development across a number of hematologic malignancies. We are advancing technologies as well as working to identify new and innovative options that address specific hematologic cancers, molecular subtypes, gene over-expression and mechanisms of resistance.

For more information, please visit www.Pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of November 29, 2012. 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 hematology pipeline in general and about BOSULIF (bosutinib) and inotuzumab ozogamicin, including their potential benefits, in particular, 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 BOSULIF (bosutinib) or inotuzumab ozogamicin as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of BOSULIF (bosutinib) or 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, 2011 and in its reports on Form 10-Q and Form 8-K.

[1] ASH Accepted Abstract #69 Assessment of Early Molecular Response as a Predictor of Long-term Clinical Outcomes in the Phase 3 BELA Study. Oral Presentation, December 9, 2012: 12:30am ET. T. Brummendorf – Presenter. 54th American Society of Hematology Annual Meeting. Atlanta, GA. December 8-11, 2012.

[2] ASH Accepted Abstract # 2793. Baseline Predictors of Response to Bosutinib in Patients With Chronic Phase Chronic Myeloid Leukemia Following Resistance or Intolerance to Imatinib Plus Dasatinib and/or Nilotinib (Study 200).General Poster Session, December 9, 2012: 6:00 – 8:00 pm ET. J. Cortes – Presenter. 54th American Society of Hematology Annual Meeting. Atlanta, GA. December 8-11, 2012.

[3] ASH Accepted Abstract #2798. Assessment of Early Cytogenetic Response as a Predictor of Long-term Clinical Outcomes in a Phase 1/2 Study of Bosutinib in Chronic Phase CML (Study 200).General Poster Session, December 9, 2012: 6:00 – 8:00 pm ET. J. Cortes – Presenter. 54th American Society of Hematology Annual Meeting. Atlanta, GA. December 8-11, 2012.

[4] ASH Accepted Abstract #3779. Bosutinib as Therapy for Chronic Phase Chronic Myeloid Leukemia Following Resistance or Intolerance to Imatinib: 36-month Minimum Follow-up Update (Study 200) General Poster Session, December 10, 2012: 6:00 – 8:00 pm ET. J. Cortes – Presenter. 54th American Society of Hematology Annual Meeting. Atlanta, GA. December 8-11, 2012.

[5] ASH Accepted Abstract #3785. Bosutinib as Therapy for Chronic Phase Chronic Myeloid Leukemia Following Failure With Imatinib Plus Dasatinib and/or Nilotinib: 24-month Minimum Follow-up Update (Study 200) General Poster Session, December 10, 2012: 6:00 – 8:00 pm ET. H. Jean Khoury – Presenter. 54th American Society of Hematology Annual Meeting. Atlanta, GA. December 8-11, 2012.

[6] ASH Accepted Abstract #1633. An Open-label, Phase 1 Study of R-CVP in Combination with InotuzumabOzogamicin in Patients with CD22-positive B-cell Non-Hodgkin's Lymphoma: Preliminary Safety and Efficacy Data. General Poster Session, December 8, 2012: 5:30 – 7:30 pm ET. M. Ogura – Presenter. 54th American Society of Hematology Annual Meeting. Atlanta, GA. December 8-11, 2012.

[7] ASH Accepted Abstract #2612. Weekly InotuzumabOzogamicin in Adult Patients with Relapsed or Refractory CD22-Positive Acute Lymphoblastic Leukemia. General Poster Session, December 9, 2012: 6:00 – 8:00 pm ET. D. DeAngelo– Presenter. 54th American Society of Hematology Annual Meeting. Atlanta, GA. December 8-11, 2012.

[8] Clinicaltrials.gov. A Study of InotuzumabOzogamicinPlus 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.

[9] Clinicaltrials.gov. A Study of InotuzumabOzogamicin versus Investigator's Choice of Chemotherapy in Patients with Relapsed or Refractory Acute Lymphoblastic Leukemia. Available here: http://www.clinicaltrials.gov/ct2/show/NCT01564784?term=inotuzumab&rank=7. Accessed April 12, 2012.

[10] Boni J et al. Modeling the Pharmacokinetic/Pharmacodynamic Platelet Response of InotuzumabOzogamicin, 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.

[11] 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.

[12] DiJoseph J et al. Antibody-Targeted Chemotherapy with CMC-544: a CD22-Targeted Immunoconjugate of Calicheamicin for the Treatment of B-Lymphoid Malignancies. *Blood.* 2004; 1-3: 1807- 1814.

[13] American Cancer Society.Non-Hodgkin Lymphoma. Available at: http://www.cancer.org/acs/groups/cid/documents/webcontent/003126-pdf.pdf. Accessed April 25, 2011.

[14] Francisco Blood 2003; ADC Message Landscape slide 17, point 3.

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