Pfizer Logo

New Phase 2 Results Show Investigational Compound Glasdegib Improved Overall Survival in Acute Myeloid Leukemia and High-Risk Myelodysplastic Syndrome

Saturday, December 03, 2016 - 08:00am

Data on First Smoothened Inhibitor to Show Clinical Benefit in This Patient Population to be Presented During Oral Session at 2016 ASH Annual Meeting

Today, Pfizer Inc. (NYSE:PFE) announced new data from a randomized Phase 2 study of glasdegib (PF-04449913), an oral, smoothened (SMO) inhibitor, showing the addition of glasdegib to low-dose cytarabine (LDAC) significantly increased overall survival (OS) when compared to LDAC alone in patients with acute myeloid leukemia (AML) or high-risk myelodysplastic syndrome (MDS) who were ineligible for intensive chemotherapy (HR: 0.501, 80% CI: 0.384, 0.654, one-sided log rank p-value 0.0003). Glasdegib is the first SMO inhibitor to show clinical benefit in this patient population. These data were presented today at the 58th American Society of Hematology (ASH) Annual Meeting and Exposition in San Diego, CA.

Glasdegib is an investigational oral therapy that inhibits the SMO receptor, thereby disrupting the hedgehog (Hh) pathway. The results presented are from a Phase 2, multicenter, randomized study that included 132 patients with previously untreated AML or high-risk MDS who were ineligible for intensive chemotherapy. Patients were treated with either LDAC 20mg subcutaneously twice daily for ten days plus oral glasdegib 100 mg daily or LDAC alone. The primary endpoint of this study was OS.

“The hedgehog pathway is a compelling target in cancer research because of the ability to target and disrupt the root of the cancer, that is the cancer-originating cell,” said Jorge Cortes, University of Texas, MD Anderson Cancer Center. “As the first smoothened inhibitor to demonstrate clinical benefit in patients with AML and high-risk MDS who were ineligible for intensive chemotherapy, these results with glasdegib provide hope that interfering with this pathway may lead to potential new treatment options for blood cancers that may improve patient outcomes.”

The results presented show that at the time of data cut-off, median OS for patients taking glasdegib plus LDAC (n=88) was 8.8 months (80% CI: 6.9, 9.9) compared to 4.9 months (80% CI: 3.5, 6.0) for patients taking LDAC only (n=44) (HR: 0.501, 80% CI: 0.384, 0.654, one-sided log rank p-value 0.0003). Low blood counts and gastrointestinal toxicities occurred more frequently among patients treated with glasdegib plus LDAC than those treated with LDAC alone. Blood infections were less among patients treated with glasdegib plus LDAC (3.6 %) compared to LDAC alone (12.2%). Patients in the glasdegib plus LDAC group experienced increased distortion of taste (23.8%), muscle spasms (20.2%) and thinning or loss of hair (10.2%). Serious AEs of febrile neutropenia were also more frequent in patients taking glasdegib plus LDAC (36.9%) compared to LDAC alone (26.8%). The most common cause of death in both arms was disease progression.

“Acute myeloid leukemia is a rapidly progressing blood cancer for which new treatment options are needed,” said Mace Rothenberg, MD, chief development officer, Oncology, Pfizer Global Product Development. “Pfizer is excited about the promising data seen in AML patients treated with glasdegib and is working to explore further opportunities to evaluate glasdegib in the treatment of this disease.”

For more information about glasdegib and other hematology products in development by Pfizer, please visit http://www.pfizer.com/pfizer_oncology_press_kit.

About Glasdegib

Glasdegib is an investigational oral therapy that inhibits the SMO receptor, thereby disrupting the hedgehog (Hh) pathway. SMO inhibition of Hh signaling impacts tumor biology by disrupting the regulation of cancer stem cell (CSC) survival. This may inhibit development of drug resistance and prevent relapse. Glasdegib is currently under investigation for select hematologic malignancies, including AML and MDS.

About Pfizer Hematology

Along with our marketed products for hematological conditions, Pfizer is advancing a broad range of therapies that leverage select pathways and mechanisms of action to address acute and chronic leukemias, myeloproliferative disorders and lymphoma. In the near-term, Pfizer is in discussions with global regulatory authorities about inotuzumab ozogamicin for the treatment of acute lymphoblastic leukemia (ALL) and Mylotarg (gemtuzumab ozogamicin) for the treatment of acute myeloid leukemia (AML).

About Pfizer Oncology

Pfizer Oncology is committed to pursuing innovative treatments that have a meaningful impact on those living with cancer. As a leader in oncology speeding cures and accessible breakthrough medicines to patients, Pfizer Oncology is helping to redefine life with cancer. Our strong pipeline of biologics, small molecules and immunotherapies is one of the most robust in the industry, and 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 its breakthrough medicines. Because Pfizer Oncology knows that success in oncology is not measured solely by the medicines you manufacture, but rather by the meaningful partnerships you make to have a more positive impact on people’s lives. Learn more about how Pfizer Oncology is applying innovative approaches to improve the outlook for people living with cancer at http://www.pfizer.com/research/therapeutic_areas/oncology.

Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of healthcare products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer healthcare products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. For more information, please visit us at www.pfizer.com. In addition, to learn more, follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube, and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: *The information contained in this release is as of December 3, 2016. 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 glasdegib (PF-04449913), inotuzumab ozogamicin and Mylotarg (gemtuzumab ozogamicin), investigational therapies, including their 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 commencement and 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; whether and when any applications for glasdegib, inotuzumab ozogamicin or Mylotarg may be filed in any jurisdictions; 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 glasdegib, inotuzumab ozogamicin and Mylotarg; 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, 2015 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors 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.

Media: Sally Beatty, 212-733-6566 or Investors: Ryan Crowe, 212-733-8160