Pfizer Reports Positive Clinical Data for BCMA-CD3 Bispecific Antibody (PF-06863135) in Multiple Myeloma

Monday, December 07, 2020 - 07:15am

.q4default .bwalignc { text-align: center; list-style-position: inside }

Subcutaneous administration demonstrates manageable safety and encouraging clinical activity

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) today announced safety and clinical response results from the ongoing Phase 1 study (NCT03269136) for PF-06863135, an investigational B-cell maturation antigen (BCMA) CD3-targeted bispecific antibody. Data from 30 patients with relapsed or refractory multiple myeloma showed manageable safety across all subcutaneous dose levels with no dose-limiting toxicities observed, and 83% of patients achieved a clinical response at the highest dose level. The results will be presented today at the Virtual American Society of Hematology (ASH) Annual Meeting and Exposition.

“Despite treatment advances, multiple myeloma remains incurable and there is a substantial need for breakthroughs for patients,” said Jeff Settleman, Senior Vice President & Chief Scientific Officer, Oncology R&D, Pfizer. “The very high response rate observed with PF-06863135, coupled with manageable safety and the convenience of subcutaneous administration, underscores the potential impact this medicine may have for people living with this devastating disease. These findings support continued development of PF-06863135 for people with multiple myeloma, both as monotherapy and in combination with standard or novel therapies.”

PF-06863135 is a bispecific antibody designed to bind to BCMA which is highly expressed on the surface of multiple myeloma cells, and the CD3 receptor found on the surface of cancer-fighting T cells, bridging them together to activate an immune response. Binding affinity to BCMA and CD3 has been optimized, enabling more potent T-cell-mediated anti-myeloma activity. Subcutaneous administration of PF-06863135 is intended to allow higher doses than intravenous administration without increasing adverse events.

The primary objectives of this portion of the study were to assess safety and tolerability of PF-06863135 administered subcutaneously, to determine the maximum tolerated dose, and to select the recommended Phase 2 dose. In the study, no dose-limiting toxicities were observed across any of the subcutaneous dose levels evaluated (80 to 1,000 µg/kg weekly) during dose escalation. Cytokine release syndrome (CRS) was reported in 73.3% of patients and was limited exclusively to grade 1 (56.7%) or grade 2 (16.7%). Grade 3 or higher adverse events (AEs) occurring in more than 10% of patients included lymphopenia (53.3%), neutropenia (26.7%), thrombocytopenia (16.7%) and anemia (16.7%).

The overall response rate (ORR) was 80% among the 20 patients treated in cohorts across the efficacious dose range of 215 to 1,000 µg/kg weekly. Among these 20 patients, six achieved stringent complete response or complete response, three achieved very good partial response, and six achieved partial response. Three responding patients had received at least one prior BCMA-targeted therapy. At the highest dose level of 1,000 µg/kg, the ORR was 83% (5/6 patients). Based on these data, 1,000 µg/kg weekly is the recommended Phase 2 dose.

About the PF-06863135 Phase 1 Trial

NCT03269136 is a Phase 1, open-label, multi-dose, multicenter, dose escalation, safety, pharmacokinetic (PK) and pharmacodynamic study of PF-06863135 for adult patients with advanced multiple myeloma who have relapsed after, or are refractory to, standard therapies. Part 1 of this two-part study assessed the safety and tolerability of increasing dose levels of PF-06863135. The study enrolled 80 patients and evaluates PF-06863135 administered intravenously or subcutaneously. Preliminary results for intravenous administration were reported at ASH in 2019.1 For more information about the trial, visit www.clinicaltrials.gov.

About Multiple Myeloma

Multiple myeloma is a blood cancer that affects plasma cells made in the bone marrow. Healthy plasma cells make antibodies that help the body fight infection. According to the

latest figures available, there are approximately 32,270 new cases of multiple myeloma diagnosed annually in the United States and 160,000 globally.2,3 Despite treatment advances, multiple myeloma remains incurable. The median survival is just over 5 years, and most patients receive four or more lines of therapy.4

About Pfizer Oncology

At Pfizer Oncology, we are committed to advancing medicines wherever we believe we can make a meaningful difference in the lives of people living with cancer. Today, we have an industry-leading portfolio of 23 approved innovative cancer medicines and biosimilars across more than 30 indications, including breast, genitourinary, colorectal, blood and lung cancers, as well as melanoma.

Pfizer Inc.: Breakthroughs that change patients' lives

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 health care products, including innovative medicines and vaccines. 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, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and 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 7, 2020. 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 PF-06863135, an investigational B-cell maturation antigen (BCMA) CD3-targeted bispecific antibody, including its 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 endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory

approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications for any potential indications for PF-06863135 may be filed in any jurisdictions; whether and when regulatory authorities in any jurisdictions may approve any such applications, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether PF-06863135 will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of PF-06863135; uncertainties regarding the impact of COVID-19 on Pfizer’s business, operations and financial results; 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, 2019 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 U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com .

_____ 1 Raje NS, et al. Safety, Clinical Activity, Pharmacokinetics, and Pharmacodynamics from a Phase I Study of PF-06863135, a B-Cell Maturation Antigen (BCMA)-CD3 Bispecific Antibody, in Patients with Relapsed/Refractory Multiple Myeloma. Blood (2019) 134 (Supplement_1):1869.https://doi.org/10.1182/blood-2019-121805 2 American Cancer Society. Key Statistics About Multiple Myeloma. Available at: https://www.cancer.org/cancer/multiple-myeloma/about/key-statistics.html. Accessed December 2020. 3 World Health Organization. Globalcan 2018: Multiple Myeloma. Available at: https://gco.iarc.fr/today/data/factsheets/cancers/35-Multiple-myeloma-fact-sheet.pdf. Accessed December 2020. 4 Mikhael, J, Ismaila N, Cheung M, et al. Treatment of multiple myeloma: ASCO and CCO joint clinical practice guideline. J Clin Onco.l 37:1228-1263.

View source version on businesswire.com: https://www.businesswire.com/news/home/20201207005166/en/

Pfizer Media Contact: Steve Danehy 978-272-2946 Steven.Danehy@pfizer.com

Pfizer Investor Contact: Bryan Dunn 212-733-8917 Bryan.Dunn@pfizer.com

Source: Pfizer Inc.