Pfizer Logo

Pfizer Announces Positive Top-Line Results For Potential Biosimilar To Rituxan®/MabThera®

Wednesday, January 24, 2018 - 03:30am

Results from the Comparative REFLECTIONS B3281006 Study Demonstrate Equivalence in Patients with Indolent Follicular Lymphoma

We are pleased to report on our fifth proposed biosimilar monoclonal antibody (mAb) with positive study results.

Pfizer Inc. today announced that REFLECTIONS B3281006, a comparative safety and efficacy study of PF-05280586 versus MabThera® (rituximab-EU), met its primary endpoint. PF-05280586 is being developed by Pfizer as a potential biosimilar to Rituxan® (rituximab-US)/MabThera®[1].

The trial demonstrated equivalence in overall response rate (ORR) for the first-line treatment of patients with CD20-positive, low tumor burden, follicular lymphoma.

“We are pleased to report on our fifth proposed biosimilar monoclonal antibody (mAb) with positive study results. These results reinforce the potential of our proposed rituximab biosimilar in providing a safe and effective treatment option for patients,” said Amrit Ray, MD, global president, Pfizer Essential Health Research and Development. “As a global leader in novel biologics, and with one of the broadest global portfolios in oncology, we are delivering on our commitment to advancing high-quality medicines for the millions of patients with cancer around the world today and in the future.”

Pfizer’s biosimilars pipeline consists of seven distinct biosimilar molecules in mid to late stage development, with three of these in oncology, as well as several others in early stage development.

About the REFLECTIONS B3281006 Study

REFLECTIONS B3281006 is a randomized, double-blind clinical trial evaluating the efficacy, safety, pharmacokinetics and immunogenicity of PF-05280586 versus MabThera® (rituximab-EU)for the first-line treatment of patients with cd20-positive, low tumor burden, follicular lymphoma. The primary endpoint measure, ORR, is defined according to the revised response criteria for malignant lymphoma [Time Frame: Week 26]. Results of the study will be presented in full at a future medical meeting or summarized in publication.

More information about the PF-05280586 REFLECTIONS B3281006 study can be found at www.clinicaltrials.gov.

About PF-05280586

PF-05280586 is a monoclonal antibody (mAb) that is in development as a potential biosimilar to Rituxan® /MabThera®. Rituxan®/MabThera® is indicated for the treatment of patients with certain types of CD20-positive non-Hodgkin's lymphoma; CD20-positive chronic lymphocytic leukemia; rheumatoid arthritis; granulomatosis with Polyangiitis and Microscopic Polyangiitis; and other region-specific indications.

PF-05280586 is an investigational compound and has not received regulatory approval in any country. Biosimilarity has not yet been established by regulatory authorities.

About Pfizer: 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 health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care 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, 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 January 24, 2018. 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-05280586 and Pfizer's proposed biosimilars pipeline, 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 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 PF-05280586 or any other biosimilars in development may be filed with regulatory authorities in any jurisdictions; whether and when regulatory authorities in any jurisdictions may approve any such applications, 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, and, if approved, whether PF-05280586 or any such other biosimilars in development will be commercially successful; intellectual property and/or litigation implications; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of PF-05280586 or any other biosimilars in development; 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, 2016, 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 10-Q and 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] Rituximab is marketed in the U.S. under the brand name Rituxan® and marketed in the E.U. and other regions under the brand name MabThera®. Rituxan® and MabThera® are registered trademarks of Genentech, Inc.

Media: Thomas Biegi, M: +1 212-733-2204 Thomas.Biegi@pfizer.com or Investors: Ryan Crowe, O: +1 212-733-8160 Ryan.Crowe@pfizer.com