Pfizer Commends The FDA Advisory Committee's Vote To Approve Proposed Biosimilar Infliximab, The First Biosimilar Monoclonal Antibody Reviewed, For All Eligible Indications

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Pfizer Inc. commends today's recommendation by the United States (U.S.) Food and Drug Administration's (FDA) Arthritis Advisory Committee to approve the investigational biosimilar infliximab (CT-P13) across all eligible indications by a vote of 21 to three. Celltrion's proposed biosimilar infliximab, to which Pfizer holds exclusive U.S. commercialization rights, is the first biosimilar monoclonal antibody (mAb) therapy to be reviewed by the FDA for licensure in the U.S., and is only the second biosimilar to be recommended for approval by a U.S. FDA Advisory Committee.

The FDA is considering the proposed biosimilar infliximab for all indications of the reference product eligible for licensure, including the treatment of rheumatoid arthritis, adult ulcerative colitis, plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and adult and pediatric Crohn's disease.

"As a leading global biosimilars company and having seen firsthand the impact of biosimilars in other countries during the past eight years, we applaud the FDA Advisory Committee for reaching this positive recommendation," said Sumant Ramachandra, M.D., Ph.D., senior vice president, Research & Development, Global Established Pharma, Pfizer

Inc. “Biosimilars represent an exciting opportunity to expand patient access to important treatments, and we are proud to be at the forefront of helping shape and prepare the U.S. market for these therapies.”

The Advisory Committee’s recommendation to approve the proposed biosimilar infliximab for all eligible indications, based on extrapolation of data, marks a critical next step in helping create a sustainable market for biosimilars in the U.S. Pfizer recognizes the importance of this milestone in more broadly advancing opportunities to expand patient access to high-quality, lower-cost alternative treatment options through biosimilars.

The FDA is not bound by the Advisory Committee’s recommendation, but the Agency takes its advice into consideration when reviewing the biologics license application (BLA) for medicinal products.

“We look forward to the FDA’s continued review and, while awaiting its decision and certain other factors, we are moving ahead with the preparation of our launch plans for 2016,” said Jenny Alltoft, global biosimilars lead, Pfizer Inc. “Pfizer remains committed to bringing these important medicines to patients in the U.S. as quickly as possible.”

Hospira, now a Pfizer company, entered into a business cooperation agreement with Celltrion in 2009 for several biosimilar products, including a potential biosimilar to Remicade® (infliximab).1 Pfizer has exclusive commercialization rights to the proposed biosimilar infliximab in the U.S. and certain other jurisdictions.

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 February 9, 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 the potential biosimilar infliximab, 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; whether and when any applications for proposed biosimilar infliximab or label updates for proposed biosimilar infliximab may be filed with regulatory authorities in any other jurisdictions; whether and when the FDA may approve the BLA for proposed biosimilar infliximab and whether and when regulatory authorities in other jurisdictions may approve any such other applications that are pending or that may be filed for proposed biosimilar infliximab, 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; intellectual property and/or litigation implications; relationship with the application sponsor; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of proposed biosimilar infliximab; 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, 2014, 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 andwww.pfizer.com.

1 Remicade® is a registered U.S. trademark of Janssen Biotech, Inc.

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