FDA Approves INFLECTRA™ (Biosimilar Infliximab), The First U.S. Biosimilar Monoclonal Antibody, For All Eligible Indications

Tuesday, April 05, 2016 - 01:34pm

NEW YORK--The United States (U.S.) Food and Drug Administration (FDA) today approved Celltrion's INFLECTRA™ (biosimilar infliximab) across all eligible indications of the reference product, Remicade® (infliximab).1INFLECTRA is now the first and only biosimilar monoclonal antibody (mAb) therapy, and only the second biosimilar, to be approved in the U.S.

Hospira, now a Pfizer company, entered into an agreement with Celltrion Inc. and Celltrion Healthcare, Co., Ltd. in 2009 for several potential biosimilar products, including INFLECTRA. Pfizer holds exclusive commercialization rights to INFLECTRA in the U.S. and certain other jurisdictions.

"The introduction of high-quality, effective biosimilars provides an opportunity to expand access to important medicines," said Salomon Azoulay, MD, senior vice president and chief medical officer, Pfizer Global Established Pharma Business. "As a leading global biologics company with several biosimilar products in our pipeline, we appreciate the significance of this milestone in developing a pathway for biosimilars to come to market in the U.S., and in helping advance their adoption in the healthcare system."

INFLECTRA is a treatment indicated for reducing signs and symptoms in patients with rheumatoid arthritis, adult ulcerative colitis, plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and adult and pediatric Crohn's disease.

The FDA approval was based on the comprehensive data package submitted by Celltrion demonstrating a high degree of similarity between INFLECTRA and the U.S. reference product, Remicade. The FDA's decision follows the February 9, 2016 FDA Arthritis Advisory Committee's recommendation to approve proposed biosimilar infliximab across all eligible indications, by a vote of 21-3.

"Our experience in other markets across the globe demonstrates that biosimilars can be a welcome option for patients, physicians and others," said Jenny Alltoft, head of global biosimilars, Pfizer Inc. "Pfizer is proud to play a leading role in preparing the U.S. market for biosimilars. We are committed to bringing these important medicines to patients in the U.S. as quickly as possible. While launch timing for INFLECTRA will ultimately depend on a number of factors such as marketplace dynamics and intellectual property considerations, we are continuing with the preparation of our launch plans for 2016."

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 April 5, 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 INFLECTRA and our 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,

uncertainties regarding the launch timing and commercial success of INFLECTRA in the United States; the uncertainties inherent in research and development; whether and when any applications for INFLECTRA or label updates for INFLECTRA may be filed with regulatory authorities in any other jurisdictions and whether and when regulatory authorities in other jurisdictions may approve any such other applications that are pending or that may be filed for INFLECTRA, 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 INFLECTRA; 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, 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 Remicade® is a registered U.S. trademark of Janssen Biotech, Inc.

Pfizer Inc. Media: Rachel Hooper, 916-708-1868 Rachel.Hooper@pfizer.com or Investors: Chuck Triano, 212-733-3901 Charles.E.Triano@pfizer.com