Pfizer Logo

FDA Approves New Pfizer Biosimilar

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Pfizer-Developed Biosimilar Medicine IXIFI™ (infliximab-qbtx) Receives FDA Approval for All Eligible Indications

Pfizer Inc. (NYSE:PFE) announced today that the United States (U.S.) Food and Drug Administration (FDA) has approved IXIFI™ (PF-06438179, infliximab-qbtx), a chimeric human-murine monoclonal antibody (mAb) against tumor necrosis factor, as a biosimilar to Remicade® (infliximab)* for all eligible indications of the reference product.[1]

The FDA has approved IXIFI as a treatment for patients with rheumatoid arthritis, Crohn's disease, pediatric Crohn’s disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis.[1]

FDA approval follows the acceptance of the IXIFI Biologics License Application in April 2017 and is based on the totality of evidence demonstrating a high degree of similarity to the reference product, including the REFLECTIONS B537-02 study in patients with moderate to severe active RA[2]. The Phase 3, multi-national, randomized, double blind, two-arm, parallel group study evaluated the safety, efficacy, and immunogenicity of IXIFI versus Remicade administered intravenously in combination with methotrexate to treat patients with moderate to severely active RA who have had an inadequate response to methotrexate therapy.[2] The study met its primary endpoint of ACR20 response (?20% improvement by American College of Rheumatology criteria) at Week 14, and was supported by data at week 30.[3]

Pfizer has a portfolio of three marketed biosimilar medicines outside the U.S. including INFLECTRA® (infliximab), Retacrit (epoetin zeta), and Nivestim (filgrastim); and a biosimilars pipeline consisting of 13 distinct biosimilar molecules in various stages of development. As part of its global biosimilars strategy, Pfizer supplies Celltrion’s INFLECTRA® (infliximab-dyyb) in the U.S. and certain other markets across the globe.

About IXIFI™
IXIFI™ (infliximab-qbtx) is a chimeric human-murine mAb against tumor necrosis factor, approved as a biosimilar for all eligible indications of the reference product.[1] IXIFI has been approved in the U.S. for rheumatoid arthritis, Crohn's disease, pediatric Crohn’s disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis.[1]

In February 2016, Sandoz acquired the rights from Pfizer for the development, commercialization and manufacture of PF-06438179 in the 28 EU member states, as well as three of the four member states of the European Free Trade Association (EFTA) (Iceland, Liechtenstein and Norway) that form the European Economic Area (EEA). Under the terms of the divestment, Pfizer retains commercialization and manufacturing rights to PF-06438179 in countries outside the EEA.[4]

Please see full Prescribing Information for IXIFI (infliximab- qbtx).

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 December 13, 2017. 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 IXIFI (PF-06438179, infliximab-qbtx), 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 possibility of unfavorable new clinical data and additional analyses of existing clinical data; whether and when any applications for IXIFI may be filed with regulatory authorities in any other jurisdictions; whether and when regulatory authorities in any such other jurisdictions (outside the U.S.) 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; intellectual property and/or litigation implications; 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.

References

[1] IXIFI (infliximab-qbtx) Prescribing Information. New York. NY: Pfizer Inc: 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761072s000lbl.pdf. Accessed December 2017.

[2] Pfizer. Pfizer Announces Positive Top-Line Results From Reflections B537-02 Study For PF-06438179 (Infliximab-Pfizer) A Potential Biosimilar To REMICADE® (Infliximab). September 2016. Available at: http://www.pfizer.com/news/press-release/press-release-detail/pfizer_announces_positive_top_line_results_from_reflections_b537_02_study_for_pf_06438179_infliximab_pfiz . Accessed December 2017.

[3] Cohen SB, Alten R, Kameda H, Rehman MI, Schumacher K, Schmitt S, Hua SY, Sewell KL. A Randomized, Double-Blind Study Comparing PF-06438179/GP1111, a Potential Infliximab Biosimilar, and Infliximab, Both in Combination with MTX, As Treatment for Patients with Moderate to Severe Active RA Who

Have Had an Inadequate Response to MTX Therapy [abstract]. *Arthritis Rheumatol.* 2017; 69 (suppl 10). Available at: http://acrabstracts.org/abstract/a-randomized-double-blind-study-comparing-pf-06438179gp1111-a-potential-infliximab-biosimilar-and-infliximab-both-in-combination-with-mtx-as-treatment-for-patients-with-moderate-to-severe-active/. Accessed December 2017.

[4] Novartis. Sandoz strengthens its biosimilars portfolio with acquisition of Pfizer's biosimilar infliximab in EEA. Available at:

https://www.novartis.com/news/media-releases/sandoz-strengthens-its-biosimilars-portfolio-acquisition-pfizers-biosimilar. Accessed December 2017.