



# Pfizer Announces Positive Top-Line Results from the Comparative REFLECTIONS B538-02 Study for PF-06410293, a Potential Biosimilar to Humira® 1 (adalimumab)

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Marks Pfizer's third proposed biosimilar pipeline molecule<sup>2</sup> to report positive top-line data results within the past four months

**"Today's announcement builds on Pfizer's robust biosimilar pipeline which has now delivered positive top-line data results for three of our proposed biosimilars"**

Pfizer Inc. (NYSE:PFE) today announced that the comparative, confirmatory REFLECTIONS B538-02 study met its primary objective by demonstrating equivalent efficacy as measured by the American College of Rheumatology 20 (ACR20) response rate at Week 12. This trial is evaluating the efficacy, safety, and immunogenicity of PF-06410293 compared to Humira® (adalimumab), each taken in combination with methotrexate, in patients with moderate to severe rheumatoid arthritis. PF-06410293 is being developed as a potential biosimilar to Humira.

"Today's announcement builds on Pfizer's robust biosimilar pipeline which has now delivered positive top-line data results for three of our proposed biosimilars," said Sumant Ramachandra, MD, PhD, MBA, Head of Research and Development, Pfizer Essential Health. "As the leading global biosimilars company, we continue to advance our commitment to expand access to high-quality treatment options for patients living with chronic, debilitating conditions, such as those in inflammation. Inflammation remains one

of the core research areas for Pfizer, spanning over 60 years and including a number of assets in various stages of development.”

This latest data announcement represents Pfizer’s second proposed inflammation biosimilar and the third proposed biosimilar pipeline molecule to report positive top-line results within the past four months. The Pfizer biosimilars pipeline consists of eight distinct biosimilar molecules in mid to late stage development, and several others in early stage development.

#### About REFLECTIONS B538-02

REFLECTIONS B538-02 is a multi-national, randomized, double blind, two-arm, parallel group equivalence study [N=597] designed to evaluate the safety, efficacy, and immunogenicity of PF-06410293 (a potential biosimilar to Humira® [adalimumab]) versus Humira in combination with methotrexate when administered subcutaneously to treat patients with moderate to severely active rheumatoid arthritis (RA) who have had an inadequate response to methotrexate therapy. The primary endpoint is an equivalent ACR20 response ( $\geq 20\%$  improvement by ACR criteria) at Week 12 of study treatment. More information about the REFLECTIONS B538-02 study can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

#### About PF-06410293

PF-06410293 is a monoclonal antibody (mAb) that is in development as a potential biosimilar to Humira® (adalimumab).

Humira is currently approved in the U.S., EU and other markets for multiple indications including rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn’s disease, pediatric Crohn’s disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa and uveitis.

PF-06410293 is an investigational compound and has not received regulatory approval in any country. Biosimilarity has not yet been established by regulatory authorities and is not yet claimed.

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, Pfizer has worked to make a difference for all who rely on us. For more information, please visit us at [www.pfizer.com](http://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](https://www.facebook.com/Pfizer).

DISCLOSURE NOTICE: The information contained in this release is as of January 5, 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 Pfizer's biosimilars pipeline and PF-06410293, 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-06410293 or any other biosimilars in development may be filed with regulatory authorities in any jurisdictions; whether and when regulatory authorities in any such jurisdictions may approve any such applications for PF-06410293 or any other biosimilars in development, 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; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of PF-06410293 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, 2015, included 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](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

1 Humira® is a registered U.S. Trademark of Abbvie Biotechnology Ltd.

2 Positive top-line results were reported for infliximab, trastuzumab and adalimumab. Regarding infliximab, in February 2016, Sandoz acquired the rights from Pfizer for the development, commercialization and manufacture of PF-06438179, a proposed biosimilar to Remicade® (infliximab), in the 28 countries 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.

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