

# Pfizer Announces Positive Top-Line Results from the Pivotal Comparative REFLECTIONS B3271002 Study for PF-05280014, a Potential Biosimilar to Herceptin®<sup>1</sup> (trastuzumab)

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Results Demonstrate Equivalence in Objective Response Rate in Patients with HER2-positive Metastatic Breast Cancer

Pfizer Inc. (NYSE:PFE) today announced that the pivotal REFLECTIONS B3271002 study, a comparative safety and efficacy study of PF-05280014 versus Herceptin® (trastuzumab), met its primary endpoint. PF-05280014 is being developed by Pfizer as a potential biosimilar to Herceptin.

The trial demonstrated equivalence in the primary endpoint of objective response rate (ORR) of PF-05280014 versus Herceptin, taken in combination with paclitaxel, in first line patients with HER2-positive metastatic breast cancer. ORR is defined as the proportion of patients with tumor size reduction of a predefined amount and for a minimum period of time<sup>2</sup>.

“As the leading global biosimilars company, we are committed to advancing our robust pipeline of biosimilar therapies in hopes of expanding access to high-quality treatment options for patients living with serious, life-threatening conditions such as cancer,” said Sumant Ramachandra, MD, PhD, MBA, Head of Research and Development, Pfizer Essential Health. “Favorable comparative clinical data between proposed biosimilars and their respective reference product contribute to physician and patient understanding of and confidence in the value and importance of biosimilars. We are encouraged by these data and look forward to sharing the complete results with health authorities and the oncology community once available.”

A separate comparative, randomized, double-blind clinical trial [REFLECTIONS B3271004] in early breast cancer patients [N=226] also met its primary endpoint of steady-state Ctrough concentrations (PK) in patients treated with PF-05280014 and Herceptin.

## About the REFLECTIONS B3271002 Study

REFLECTIONS B3271002 is a comparative, randomized, double blind, clinical trial[N=690] evaluating the efficacy, safety, pharmacokinetics (PK) and immunogenicity of PF-05280014 (a potential biosimilar to Herceptin® [trastuzumab]) in combination with paclitaxel versus Herceptin in combination with paclitaxel in first line patients with HER2-positive metastatic breast cancer. The primary endpoint is objective response rate (ORR) by Week 25 of study treatment. ORR is defined as the proportion of patients with tumor size reduction of a predefined amount and for a minimum period of time<sup>2</sup>.

More information about the PF-05280014 REFLECTIONS B3271002 and B3271004 studies can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

## **About PF-05280014**

PF-05280014 is a monoclonal antibody (mAb) that is in development as a potential biosimilar for all currently approved indications of Herceptin® (trastuzumab).

Herceptin is currently approved in the U.S., EU and other markets for HER2-positive breast cancer and gastric cancer.

PF-05280014 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](https://twitter.com/Pfizer) and [@Pfizer\\_News](https://twitter.com/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 November 30, 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 PF-05280014, 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 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-05280014 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-05280014, 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-05280014; 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](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).*

1 Herceptin® is a registered US trademark of Genentech, Inc.

2 United States Food and Drug Administration. Guidance for Industry: Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics. Available at:

<http://www.fda.gov/downloads/Drugs/.../Guidances/ucm071590.pdf>. Accessed October 27, 2016.

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