



# Pfizer Presents Positive Pivotal Data for PF-05280014, an Investigational Biosimilar to Herceptin® (trastuzumab), at the European Society for Medical Oncology (ESMO) 2017 Congress

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Data from the REFLECTIONS B327-02 study demonstrates equivalence in objective response rate (ORR) for patients with HER2-positive metastatic breast cancer. Marketing applications accepted for review by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA)

Pfizer Inc. (NYSE:PFE) today announced positive findings from REFLECTIONS B327-02 (n=707), a pivotal Phase 3 randomized, double-blind comparative safety and efficacy study of the company's investigational trastuzumab biosimilar (PF-05280014) versus Herceptin®1 (trastuzumab), at the European Society for Medical Oncology (ESMO) 2017 Congress in Madrid. Positive data from a supplemental study, REFLECTIONS B327-04 (n=226), were also presented at the meeting. PF-05280014 is being developed by Pfizer as a potential biosimilar to Herceptin.

"Biosimilars are poised to revolutionize the oncology treatment landscape by expanding patient access to high quality and effective therapies," said Dr. Mark Pegram, associate director for clinical research at the Stanford Comprehensive Cancer Institute, and director of the Breast Oncology Program at the Stanford Women's Cancer Center. "These data are

encouraging, and reinforce the future potential of Pfizer's investigational trastuzumab biosimilar to help meet the needs of cancer patients and their treating physicians as a potentially lower cost option to Herceptin, across all indications."

The REFLECTIONS B327-02 study achieved the primary objective for equivalence in the objective response rate (ORR) of PF-05280014 versus Herceptin in patients receiving first-line treatment, in combination with paclitaxel, for HER2-positive metastatic breast cancer [risk ratio of 0.940; within the pre-specified equivalence margin of 0.8–1.25]. 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> Additionally, rates of one year progression-free survival and one year survival were similar across groups (56% and 88.84% vs. 52% and 87.96% for PF-05280017 and Herceptin, respectively).

The REFLECTIONS B327-04 study found there were no clinically meaningful differences between PF-05280014 and Herceptin in terms of efficacy, safety, immunogenicity, and noninferiority in pharmacokinetics, as neoadjuvant treatment taken in combination with docetaxel and carboplatin for patients with operable HER2-positive breast cancer.

"Pfizer is committed to driving significant improvements in patient care through the development of high quality, effective biosimilars. Including PF-05280014, Pfizer's biosimilars pipeline consists of eight distinct biosimilar molecules in mid to late stage development, with three of these in oncology," said Salomon Azoulay, MD, Senior Vice President, Chief Medical Officer, Pfizer Essential Health. "By continuing to grow our oncology and supportive care presence through both novel therapies and biosimilars, we are able to provide an array of important treatment options for patients, physicians and healthcare systems."

As part of Pfizer's commitment to expanding its oncology biosimilars pipeline, the company is progressing its biosimilar trastuzumab marketing applications, which have been accepted for review by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

#### 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, 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](http://www.pfizer.com). In addition, to learn more, please visit us on [www.pfizer.com](http://www.pfizer.com) and 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 September 10, 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 PF-05280014 and Pfizer's proposed 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, 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 or any other biosimilars in development may be filed with regulatory authorities in any jurisdictions other than the U.S. and the EU; whether and when the FDA, the EMA and regulatory authorities in any such other jurisdictions may approve any such applications for PF-05280014 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-05280014 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, 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](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

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1 Herceptin® is a registered 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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