



# Pfizer Announces Positive Top-Line Results from the Comparative REFLECTIONS B7391003 Study for PF-06439535, a Potential Biosimilar to Avastin®<sup>1</sup> (bevacizumab)

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Results demonstrate equivalence in objective response rate in patients with advanced non-squamous non-small cell lung cancer

Pfizer Inc. (NYSE:PFE) today announced that the REFLECTIONS B7391003 study, a comparative, confirmatory safety and efficacy study of PF-06439535 versus Avastin® (bevacizumab), met its primary objective. PF-06439535 is being developed by Pfizer as a potential biosimilar to Avastin.

The trial demonstrated equivalence in the primary endpoint of objective response rate (ORR) of PF-06439535 versus Avastin, taken in combination with carboplatin/paclitaxel, for the first line treatment of patients with advanced non-squamous non-small cell lung cancer (NSCLC).

“We are encouraged by this data, and its importance in helping to advance physician confidence in, and understanding of, the potential value of biosimilar medicines for cancer patients around the world,” said Salomon Azoulay, MD, Senior Vice President, Chief Medical Officer, Pfizer Essential Health. “As Pfizer’s second proposed oncology monoclonal antibody biosimilar to achieve positive top line data results, we continue to focus on and commit to advancing our pipeline of proposed biosimilars, with the goal of expanding patient access to these important therapeutic options.”

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

### **About the REFLECTIONS B7391003 Study**

REFLECTIONS B7391003 is a comparative, randomized, double blind, clinical trial [N=719] evaluating the efficacy, safety, pharmacokinetics (PK) and immunogenicity of PF-06439535 (a potential biosimilar to Avastin® [bevacizumab]) in combination with carboplatin/paclitaxel versus Avastin in combination with carboplatin/paclitaxel for the first line treatment of patients with advanced non-squamous non-small cell lung cancer (NSCLC). The primary endpoint is objective response rate (ORR) which is defined as the proportion of patients with tumor size reduction of a predefined amount and for a minimum period of time.

More information about the PF-06439535 REFLECTIONS B7391003 study studies can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **About PF-06439535**

PF-06439535 is a monoclonal antibody (mAb) that is in development as a potential biosimilar to Avastin® (bevacizumab). Avastin is approved in the U.S., EU and other regions for the treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous lung cancer (NSCLC) in addition to metastatic carcinoma of the colon or rectum; metastatic renal cell carcinoma; and other region-specific indications.

PF-06439535 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 July 24, 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-06439535 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-06439535 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-06439535 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-06439535 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).

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

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