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Pfizer Receives Positive CHMP Opinion for Oncology Biosimilar, ZIRABEV™ (bevacizumab)

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ZIRABEV ™ (bevacizumab), a potential biosimilar to Avastin ®* (bevacizumab), is Pfizer's second therapeutic oncology biosimilar to receive a positive CHMP opinion in Europe in 2018

Pfizer Inc. (NYSE:PFE) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion, recommending marketing authorization for ZIRABEV™ (bevacizumab), a potential biosimilar to Avastin (bevacizumab).[1] ZIRABEV is a monoclonal antibody for the treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer, unresectable advanced, metastatic or recurrent non-small cell lung cancer (NSCLC), advanced and/or metastatic renal cell cancer and persistent, recurrent or metastatic carcinoma of the cervix.[2]

"If approved, ZIRABEV has the potential to expand access to this life-changing biologic cancer therapy for appropriate patients and healthcare professionals across Europe," said Joe McClellan, Vice President, Biosimilars Development at Pfizer. "Today's positive CHMP opinion underscores Pfizer's strong heritage in oncology and its ongoing commitment to bringing high-quality biosimilars to market, providing additional options for people living with certain cancers."

The regulatory submission is supported with a comprehensive data package and evidence demonstrating biosimilarity to the originator product. This includes results from the phase 3 REFLECTIONS B739-03 clinical comparative study, which demonstrated clinical equivalence and found no clinically meaningful differences between ZIRABEV and Avastin in patients with advanced non-squamous NSCLC.[3] As part of the overall REFLECTIONS clinical trial program, ZIRABEV has been studied in approximately 400 subjects.[3,4]

ZIRABEV is Pfizer's second therapeutic oncology biosimilar to receive a positive CHMP opinion from the EMA in 2018.[5] Pfizer has a robust portfolio of potential biosimilar candidates in mid to late stage development and we are confident about our ability to bring these important medicines to the patients who need them around the world.[6]

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 14, 2018. 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 ZIRABEV, Pfizer's potential bevacizumab biosimilar, and Pfizer's biosimilars portfolio, including their potential benefits, that involve 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 clinical 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; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when applications for ZIRABEV or any other potential biosimilars may be filed in any other jurisdictions; whether and when the European Commission may approve the pending application for ZIRABEV in the EU and whether and when any such other applications for ZIRABEV or other potential biosimilars that may be pending or filed may be approved by regulatory authorities, 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 and, if approved, whether ZIRABEV or such other potential biosimilars will be commercially successful; intellectual property and/or litigation implications; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of ZIRABEV or other potential biosimilars; 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, 2017 and in its subsequent reports on Form 10-Q, 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 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.

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* Avastin® is a registered trademark of Genentech

[1] European Commission Community Register. Zirabev Product Information. Available at: https://www.ema.europa.eu/documents/smop-initial/chmp-summary-positive-opinion-zirabev_en.pdf Accessed December 2018.

[2] European Medicines Agency. Avastin. EPAR Summary of Product Characteristics. Available at https://www.ema.europa.eu/documents/overview/avastin-epar-summary-public_en.pdf. Accessed December 2018.

[3] Socinski MA., Von Pawel J., Kasahara K., et al. A comparative clinical study of PF-06439535, a candidate bevacizumab biosimilar, and reference bevacizumab, in patients with advanced nonsquamous non-small cell lung cancer. Abstract 109. Presented at ASCO 2018.

[4] Knight, B., Rassam, D., Liao, S. et al. A phase I pharmacokinetics study comparing PF-06439535 (a potential biosimilar) with bevacizumab in healthy male volunteers. Cancer Chemother Pharmacol (2016) 77: 839-846.

[5] European Medicines Agency. Trazimera. EPAR Medicine Overview. Available at https://www.ema.europa.eu/documents/overview/trazimera-epar-medicine-overview_en.pdf. Accessed December 2018.

[6] Pfizer Pipeline (as of October 30, 2018). Pfizer. Available at https://www.pfizer.com/sites/default/files/product-pipeline/Pipeline_Update_30OCT2018.pdf. Accessed December 2018.

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