

Pfizer Receives European Approval for ZIRABEV™ (bevacizumab), a Biosimilar to Avastin®*

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Pfizer Inc. (NYSE: PFE) today announced the European Commission (EC) has approved ZIRABEV™ 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.^{1,2}

“Pfizer is dedicated to increasing access to biosimilars for patients suffering from serious illnesses and helping create a more sustainable healthcare system,” said Andreas Penk, M.D., regional president, Oncology International Developed Markets at Pfizer. “We are proud that ZIRABEV was approved today as our second oncology biosimilar in Europe. This milestone reflects our ongoing commitment to biosimilars as we continue to bring high-quality medicines to market that may help generate cost savings for cancer care.”

* Avastin® is a registered trademark of Genentech

The EC approval is based on a comprehensive submission package which demonstrated biosimilarity of ZIRABEV and the originator product. This includes results from the phase 3 REFLECTIONS B739-03 clinical comparative study, which showed clinical equivalence and found no clinically meaningful differences between ZIRABEV and the originator product 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}

This approval follows the positive recommendation from the Committee for Medicinal Products for Human Use in December 2018.⁵ ZIRABEV has also been filed for regulatory approval with the U.S. Food and Drug Administration.

Pfizer has a robust portfolio of potential biosimilar candidates in mid- to late-stage development.⁶ ZIRABEV is Pfizer’s fifth biosimilar approved for use in Europe.^{1,7, 8,9,10}

About ZIRABEV (bevacizumab biosimilar)

ZIRABEV is a monoclonal antibody (mAb) biosimilar of the originator biologic medicine, Avastin®, which works by inhibiting the formation of new blood vessels (angiogenesis) by specifically recognizing and binding to vascular endothelial growth factor (VEGF) protein.^{11, 12,13} ZIRABEV has been studied in nearly 400 patients.^{3,4}

ZIRABEV safety information

Do not use ZIRABEV if you are allergic to bevacizumab, any of its ingredients, Chinese hamster ovary (CHO) cell products, or other recombinant human or humanised antibodies, or if you are pregnant.

Before starting treatment with ZIRABEV, tell your healthcare provider if:

- you have any conditions causing inflammation inside the abdomen (e.g. diverticulitis, stomach ulcers, colitis associated with chemotherapy)
- you have persistent, recurrent or metastatic cervical cancer
- you are going to have an operation, if you have had major surgery within the last 28 days or if you still have an unhealed wound following surgery
- you had holes in the gut wall or problems with wound healing
- you have high blood pressure which is not well controlled with blood pressure medicines
- you are over 65 years old, if you have diabetes, or if you have had previous blood clots in your arteries
- you or your family tend to suffer from bleeding problems or you are taking medicines to thin the blood for any reason
- you have metastatic cancer affecting your brain
- you have noticed coughing or spitting blood
- you have ever received anthracyclines (for example doxorubicin, a specific type of chemotherapy used to treat some cancers) or had radiotherapy to your chest, or if you have heart disease
- you have previously experienced problems after injections, such as dizziness/feeling of fainting, breathlessness, swelling or skin rash
- you have headache, vision changes, confusion or seizure with or without high blood pressure
- you have or have had pain in the mouth, teeth and/or jaw, swelling or sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth
- you need to undergo an invasive dental treatment or dental surgery, in particular when you are also receiving or have received an injection of bisphosphonate into your blood
- you are currently using or recently used a medicine called sunitinib malate, are receiving platinum- or taxane-based chemotherapy (medicines used to treat cancer) or are receiving or recently received radiotherapy
- you have previously received any other treatment for cancer

ZIRABEV increases the risk of having protein in your urine, especially if you already have high blood pressure. ZIRABEV can also increase the risk of developing blood clots in your veins (a type of blood vessel) and may cause infections and a decreased number of your neutrophils (a type of blood cell important for your protection against bacteria).

Like all medicines, ZIRABEV can cause side effects, although not everybody gets them. If you have an allergic reaction, contact your doctor or a member of medical staff straight away. The signs may include difficulty in breathing or chest pain. You could also experience redness or flushing of the skin or a rash, chills and shivering, feeling sick (nausea) or being sick (vomiting). Very common severe side effects of treatment with ZIRABEV are:

- high blood pressure
- the feeling of numbness or tingling in hands or feet
- a decreased number of cells in the blood, including white cells that help to fight infection (this may be accompanied by fever), and cells that help the blood to clot
- feeling weak and having no energy
- tiredness
- diarrhoea, nausea, vomiting and abdominal pain.

Other very common side effects that are not as severe include constipation, loss of appetite, fever, problems with eyes (including increased tear production), changes in speech, changes in sense of taste, runny nose, dry skin, flaking and inflammation of skin, changes in skin color, loss of body weight and nose bleeds. You should tell your healthcare provider immediately if you notice any of the above symptoms.

Tell your healthcare provider if you are taking, have recently taken or may take any other medicines.

Tell your healthcare provider if you are pregnant, plan to become pregnant, or are breastfeeding.

Ask your healthcare provider about the risks and benefits of ZIRABEV. Only a healthcare provider can decide if ZIRABEV is right for you.

You are encouraged to report negative side effects to the European Medicines Agency. Visit <http://www.adrreports.eu/>. Please refer to the European Summary of Product Characteristics for ZIRABEV for complete safety information.

About Pfizer Oncology

At Pfizer Oncology, we are committed to advancing medicines wherever we believe we can make a meaningful difference on the lives of patients. Today, Pfizer Oncology has an industry-leading portfolio of 18 approved innovative cancer medicines and biosimilars across more than 20 indications, including breast, prostate, kidney, lung and hematology. We also have several assets in mid- to late-stage development for the treatment of cancer or as supportive care. Pfizer Oncology is striving to change the trajectory of cancer.

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](https://twitter.com/Pfizer) and [@Pfizer_News](https://twitter.com/Pfizer_News), [LinkedIn](https://www.linkedin.com/company/pfizer), [YouTube](https://www.youtube.com/pfizer) 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 February 19, 2019. 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 bevacizumab biosimilar and an approval by the European Commission, 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, uncertainties regarding the commercial success of ZIRABEV; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by

regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when applications for ZIRABEV may be filed in any other jurisdictions; whether and when any such other applications for ZIRABEV that may be pending (including the application pending in the United States) or filed may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether ZIRABEV will be commercially successful; intellectual property and/or litigation implications; decisions by regulatory authorities impacting, labeling, manufacturing processes and/or other matters that could affect the availability or commercial potential of ZIRABEV; 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.

¹ Pfizer. Data on File. European Commission Approval Letter 2019.

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 February 2019.

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 Commission Community Register. Zirabev Product Information. Available at: https://www.ema.europa.eu/documents/smop-initial/chmp-summary-positive-opinion-zirabev_en.pdf Accessed February 2019.

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 February 2019.

⁷ European Medicines Agency. European public assessment report (EPAR) for RETACRIT. Available at <https://www.ema.europa.eu/en/medicines/human/EPAR/retacrit>. Accessed February 2019.

⁸ European Medicines Agency. European public assessment report (EPAR) for INFLECTRA. Available at <https://www.ema.europa.eu/en/medicines/human/EPAR/inflectra>. Accessed February 2019.

⁹ European Medicines Agency. European public assessment report (EPAR) for NIVESTIM. Available at <https://www.ema.europa.eu/en/medicines/human/EPAR/nivestim>. Accessed February 2019.

¹⁰ European Medicines Agency. European public assessment report (EPAR) for TRAZIMERA. Available at <https://www.ema.europa.eu/en/medicines/human/EPAR/trazimera>. Accessed February 2019.

¹¹ National Cancer Institute. Angiogenesis Inhibitors. Available at <https://www.cancer.gov/about-cancer/treatment/types/immunotherapy/angiogenesis-inhibitors-fact-sheet>.

¹² Avastin.com. How is Avastin designed to work? Available at <https://www.avastin.com/patient/mcrc/about/how-avastin-works.html>. Accessed February 2019.

¹³ Avastin-HCP.com. About Avastin: Proposed Mechanism of Action. Available at <https://www.avastin-hcp.com/about-avastin/proposed-moa.html>. Accessed February 2019.

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