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EC approves Pfizer's ZIRABEV, a biosimilar to Avastin

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ZIRABEV is Pfizer’s fifth biosimilar approved for use in Europe

Pfizer recently announced that 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.

“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.”

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. ZIRABEV is Pfizer’s fifth biosimilar approved for use in Europe.