

Pfizer announces EC approval of its oncology biosimilar

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The European Commission decision marks the approval of Pfizer's first therapeutic oncology bio-similar.



Pfizer Inc. has announced that the European Commission (EC) has approved TRAZIMERA(trastuzumab), for the treatment of human epidermal growth factor (HER2) overexpressing breast cancer and HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. This approval follows the recommendation from the Committee for Medicinal Products for Human Use in May 2018.

"TRAZIMERA has the potential to help many patients with HER2 overexpressing cancers, such as breast and gastric, which can correlate with poor outcomes and aggressive disease," said Professor Diana Lüftner, Charité Campus Benjamin Franklin and Member of the Presidency of the German Society of Hematology and Medical Oncology. "Today's approval will help enable greater access for patients and physicians across Europe, without compromising on quality, efficacy and safety."

Richard Blackburn, Global President, Pfizer Essential Health Europe, Africa/Middle East and Biosimilars said "The approval of TRAZIMERA, Pfizer's first oncology biosimilar, is another significant step in our quest to introduce more treatment options for patients in Europe. Pfizer is investing in developing and launching a range of biosimilars which can help to reduce healthcare costs and increase patient access to important medicines."

The EC approval is based on a comprehensive submission package which demonstrated a high degree of similarity for TRAZIMERA and the originator product. The data included results from the REFLECTIONS B327-02 clinical comparative study, which showed clinical equivalence and found no clinically meaningful differences between TRAZIMERA and originator product in patients with first line HER2 overexpressing metastatic breast cancer.

TRAZIMERA is Pfizer's fourth biosimilar, and the first oncology biosimilar, to receive European approval. Pfizer's biosimilars pipeline consists of 9 distinct Pfizer and legacy Hospira biosimilar molecules in various stages of development.