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Pfizer Receives European Approval for Oncology Biosimilar, TRAZIMERA™ (trastuzumab)

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The European Commission decision marks the approval of Pfizer's first therapeutic oncology biosimilar

Pfizer Inc. (NYSE:PFE) today announced the European Commission (EC) has approved TRAZIMERA™,[1] a biosimilar to Herceptin®* (trastuzumab), for the treatment of human epidermal growth factor (HER2) overexpressing breast cancer and HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.[2] This approval follows the recommendation from the Committee for Medicinal Products for Human Use in May 2018.[1]

"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,"[3,4] 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.[5,6,7]

TRAZIMERA is Pfizer's fourth[8,9,10] 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.

* Herceptin® is a registered trademark of Genentech – A Member Of The Roche Group

About TRAZIMERA (trastuzumab biosimilar)

TRAZIMERA is a monoclonal antibody (mAb) biosimilar of the originator biologic medicine, Herceptin, which targets HER2, a protein found on the surface of some cancer cells which can stimulate the cells to divide and grow.[11] It locks on to the HER2 protein and blocks the receptor, stopping cell division and growth.[11]

TRAZIMERA has been studied in nearly 500 patients and across more than 20 countries to date as part of the REFLECTIONS studies.[5,6,7,12,13]

TRAZIMERA safety information

Do not use TRAZIMERA if you are allergic to trastuzumab or any of its ingredients, if you have severe breathing problems at rest due to your cancer or if you need oxygen treatment.

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

- you have had heart failure, coronary artery disease, heart valve disease (heart murmurs), high blood pressure, taken any high blood pressure medicine or are currently taking any high blood pressure medicine.
- you have ever had or are currently using a medicine called doxorubicin or epirubicin (medicines used to treat cancer).
- you suffer from breathlessness, especially if you are currently using a taxane.
- you have ever had any other treatment for cancer.

Like all medicines, TRAZIMERA can cause side effects, although not everybody gets them. The most common side-effects during a TRAZIMERA infusion are chills, fever and other flu like symptoms. Other infusion-related symptoms include nausea, vomiting, pain, increased muscle tension and shaking, headache, dizziness, breathing difficulties, wheezing, high or low blood pressure, heart rhythm disturbances (palpitations, heart fluttering or irregular heart beat), swelling of the face and lips, rash and feeling tired. These effects mainly occur with the first intravenous infusion (“drip” into your vein) and during the first few hours after the start of the infusion, and are usually temporary. Occasionally, symptoms start later than six hours after the infusion begins. If this happens to you, contact your healthcare provider immediately.

Other side effects can occur at any time during treatment with TRAZIMERA, not just related to an infusion. Heart problems can sometimes occur during treatment and occasionally after treatment has stopped and can be serious. They include weakening of the heart muscle possibly leading to heart failure, inflammation (swollen, red, hot, and in pain) of the lining around the heart and heart rhythm disturbances. This can lead to symptoms such as:

- breathlessness (including breathlessness at night),
- cough,
- fluid retention (swelling) in the legs or arms,
- palpitations (heart fluttering or irregular heart beat).

Your doctor will monitor your heart regularly during and after treatment but you should tell your doctor immediately if you notice any of the above symptoms.

If you experience any of the above symptoms when your treatment with TRAZIMERA has finished, you should see your doctor and tell them that you have previously been treated with trastuzumab.

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 TRAZIMERA. Only a healthcare provider can decide if TRAZIMERA is right for you.

You are encouraged to report negative side effects to the European Medicines Agency. Visit http://www.adrreports.eu/.

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 July 31, 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 TRAZIMERA, Pfizer's trastuzumab 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 TRAZIMERA; 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 TRAZIMERA may be filed in any other jurisdictions; whether and when any such other applications for TRAZIMERA that may be pending (including the application pending with the FDA, for which the company received a complete response letter) 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 TRAZIMERA 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 TRAZIMERA 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. Pfizer Receives Positive CHMP Opinion For Oncology Biosimilar, Trazimera™ (Trastuzumab). June 2018. Available at: https://www.pfizer.com/news/press-release/press-release-detail/pfizer_receives_positive_chmp_opinion_for_oncology_biosimilar_trazimera_trastuzumab Accessed June

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[5] Pegram M, Tan-Chiu E, Freyman A, et al. Abstract 238PD. A randomized, double-blind study of PF-05280014 (a potential trastuzumab biosimilar) vs trastuzumab, both in combination with paclitaxel, as first-line treatment for HER2-positive metastatic breast cancer. Presented at ESMO 2017.

[6] Lammers PE, Dank M, Masetti R, et al. A randomized, double-blind study of PF-05280014 (a potential biosimilar) vs trastuzumab, both given with docetaxel (D) and carboplatin (C), as neoadjuvant treatment for operable human epidermal growth factor receptor 2-positive (HER2+) breast cancer. Abstract 154PD. Presented at ESMO 2017

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[8] European Medicines Agency. European public assessment report (EPAR) for RETACRIT. Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000872/human_med_001031.jsp&mi Accessed June 2018.

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[11] Macmillan Cancer Support. Trastuzumab. (Herceptin) Available at https://www.macmillan.org.uk/cancerinformation/cancertreatment/treatmenttypes/biologicaltherapies/monoclonalantibo Accessed June 2018

[12] Clinicaltrials.gov. NCT01989676. A study of PF-05280014 [trastuzumab-Pfizer] or Herceptin (trastuzumab) plus paclitaxel in HER2 positive first line metastatic breast cancer treatment (REFLECTIONS B327-02). Available at https://clinicaltrials.gov/ct2/show/NCT01989676?term=NCT01989676&rank=1. Accessed June 2018

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