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U.S. FDA Approves Pfizer's Oncology Biosimilar TRAZIMERA™ (trastuzumab-qyyp), a Biosimilar to Herceptin®1

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Pfizer Inc. (NYSE: PFE) today announced the United States (U.S.) Food and Drug Administration (FDA) has approved TRAZIMERA™ (trastuzumab-qyyp), a biosimilar to Herceptin® (trastuzumab),[1] for the treatment of human epidermal growth factor receptor-2 (HER2) overexpressing breast cancer and HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.[2]

"This is an important milestone in the U.S. which both adds to our growing portfolio of oncology treatments and has the potential to improve access to cancer care," said Andy Schmeltz, Global President, Pfizer Oncology. "We are proud to be able to offer treatment options that can help address the diverse needs of patients."

The FDA approval was based on review of a comprehensive data package, which demonstrated a high degree of similarity between TRAZIMERA and the originator product. This includes results from the REFLECTIONS B327-02 clinical comparative study that was recently published in the *British Journal of* Cancer, which showed clinical equivalence, finding a high degree of similarity and no clinically meaningful differences between TRAZIMERA and the originator product in patients with first line HER2 overexpressing metastatic breast cancer.[3]

"Approximately 15-30% of breast cancers and 10-30% of gastric cancers are HER2-positive, which is associated with aggressive disease and poor prognoses for patients," said Dr. Mark Pegram, associate director for clinical research at the Stanford Comprehensive Cancer Institute, and director of the Breast Oncology Program at the Stanford Women's Cancer Center.[4] "With the availability of biosimilars like TRAZIMERA in the U.S., oncologists will have additional treatment options to choose from, which may help provide patients with greater access to the medicines they need."

Pfizer has a robust portfolio of potential biosimilar candidates in mid- to late-stage development.[5] TRAZIMERA is Pfizer's first oncology monoclonal antibody (mAb) biosimilar and Pfizer's fifth biosimilar to be approved by the FDA.[2,6,7,8,9] TRAZIMERA was also approved for use in the EU in July 2018 for the treatment of HER2 overexpressing breast cancer and HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.[10]

About TRAZIMERA (trastuzumab-qyyp)

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] TRAZIMERA locks on to the HER2 protein and blocks the receptors, stopping cell division and growth.

As part of the REFLECTIONS clinical trial program, TRAZIMERA has been studied in nearly 500 patients and across more than 20 countries to date.[12,13,14,15,16]

TRAZIMERA IMPORTANT SAFETY INFORMATION

Possible Serious Side Effects With TRAZIMERA (trastuzumab–qyyp)

Not all people have serious side effects, but side effects with TRAZIMERA therapy are common.

Although some people may have a life-threatening side effect, most do not.

Your doctor will stop treatment if any serious side effects occur.

TRAZIMERA is not for everyone. Be sure to contact your doctor if you are experiencing any of the following:

HEART PROBLEMS

These include heart problems—such as congestive heart failure or reduced heart function—with or without symptoms. The risk for and seriousness of these heart problems were highest in people who received both trastuzumab and a certain type of chemotherapy (anthracycline). In a study of adjuvant (early) breast cancer, one patient died of significantly weakened heart muscle. Your doctor will check for signs of heart problems before, during, and after treatment with TRAZIMERA.

INFUSION REACTIONS, including:

- Fever and chills
- Feeling sick to your stomach (nausea)
- Throwing up (vomiting)
- Pain (in some cases at tumor sites)
- Headache
- Dizziness
- Shortness of breath

These signs usually happen within 24 hours after receiving TRAZIMERA.

Be sure to contact your doctor if you:

Are a woman who could become pregnant, or may be pregnant

TRAZIMERA may result in the death of an unborn baby or birth defects. Contraception should be used while receiving TRAZIMERA and after your last dose of TRAZIMERA. If you are exposed to TRAZIMERA during pregnancy or within 7 months of becoming pregnant, you are encouraged to report TRAZIMERA exposure to Pfizer at 1-800-438-1985.

Have any signs of **SEVERE LUNG PROBLEMS**, including:

- Severe shortness of breath
- Fluid in or around the lungs

- Weakening of the valve between the heart and the lungs
- Not enough oxygen in the body
- Swelling of the lungs
- Scarring of the lungs

Your doctor may check for signs of severe lung problems when he or she examines you.

Have **LOW WHITE BLOOD CELL COUNTS**

Low white blood cell counts can be life threatening. Low white blood cell counts were seen more often in patients receiving trastuzumab plus chemotherapy than in patients receiving chemotherapy alone.

Your doctor may check for signs of low white blood cell counts when he or she examines you.

Side Effects Seen Most Often With trastuzumab

Some patients receiving trastuzumab for breast cancer had the following side effects:

- Fever
- Feeling sick to your stomach (nausea)
- Throwing up (vomiting)
- Infusion reactions
- Diarrhea
- Infections
- Increased cough
- Headache
- Feeling tired
- Shortness of breath
- Rash
- Low white and red blood cell counts
- Muscle pain

Some patients receiving trastuzumab for metastatic stomach cancer had the following side effects:

- Low white blood cell counts
- Diarrhea
- Feeling tired
- Low red blood cell counts
- Swelling of the mouth lining
- Weight loss
- Upper respiratory tract infections
- Fever
- Low platelet counts
- Swelling of the mucous membranes
- Swelling of the nose and throat
- Change in taste

You should contact your doctor immediately if you have any of the side effects listed above.

Please see full Prescribing Information for TRAZIMERA (trastuzumab-qyyp), including BOXED WARNING.

About Pfizer Oncology

At Pfizer Oncology, we are committed to advancing medicines wherever we believe we can make a meaningful difference in 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. 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 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 March 11, 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 TRAZIMERA (trastuzumab-qyyp), including its potential benefits, that involves 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 launch timing and commercial success of TRAZIMERA in the United States; 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 unfavourable new clinical data and 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 TRAZIMERA may be filed in any other jurisdictions; whether and when any such other applications for TRAZIMERA that may be pending 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 TRAZIMERA will be commercially successful; intellectual property and/or litigation implications; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or 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, 2018 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] Herceptin® is a registered trademark of Genentech Inc.
[2] TRAZIMERA™ (trastuzumab-qyyp) Prescribing Information. New York. NY: Pfizer Inc: 2019. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761081s000lbl.pdf.
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[13] 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.
[14] Yin D, Barker K B, Li R, et al. A randomized phase 1 pharmacokinetic trial comparing the potential biosimilar PF-05280014 with trastuzumab in healthy volunteers (REFLECTIONS B327-01). *BR J Clin Pharmacol.* 2014. 78(6): 1281-90.
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