Pfizer Receives Positive CHMP Opinion for Oncology Biosimilar, TRAZIMERA™ (trastuzumab)

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TRAZIMERA, a potential biosimilar to Herceptin ® (trastuzumab), is Pfizer's first therapeutic oncology biosimilar to undergo regulatory review in Europe

Pfizer Inc. (NYSE:PFE) today announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion, recommending marketing authorization for TRAZIMERA™, a potential biosimilar to Herceptin® (trastuzumab), for the treatment of HER2 overexpressing breast cancer and HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.1

"Pfizer is extremely proud to offer expanded biologic treatment options for patients by bringing more affordable, life changing biosimilar medicines to market, and today's positive recommendation from the CHMP marks one more step forward. TRAZIMERA has the potential to help many patients with HER2 overexpressing cancers across Europe and, if approved, would help address the evolving needs of healthcare systems, physicians, payers and patients, "said Amrit Ray, MD, MBA, Global President, Research & Development, Pfizer Essential Health.

The regulatory submission is supported with a comprehensive data package and totality of evidence demonstrating a high degree of similarity to the originator product. This includes results from the primary REFLECTIONS B327-02 clinical comparative study, which demonstrated clinical equivalence and found no clinically meaningful differences between TRAZIMERA and Herceptin in patients with first line HER2 overexpressing metastatic breast cancer. As part of the REFLECTIONS clinical trial program for the

proposed biosimilar trastuzumab, TRAZIMERA has been studied in nearly 500 patients and across more than 20 countries to date.2,3,4

“Many patients with breast and gastric cancers have an HER2 overexpression, which can correlate with poor outcomes and aggressive disease,” 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.5,6 “With the availability of biosimilars like TRAZIMERA in Europe, oncologists will have additional treatment options to choose from, which potentially helps our patients have greater access to these medicines.”

TRAZIMERA is Pfizer’s fourth7,8,9 biosimilar and first therapeutic oncology biosimilar to receive a positive CHMP opinion from the EMA. Pfizer’s biosimilars pipeline is progressing and consists of 11 distinct Pfizer and legacy Hospira biosimilar molecules in various stages of development.

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 June 1, 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 proposed trastuzumab biosimilar, including its 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, 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 the European Commission may approve the pending application for TRAZIMERA in the EU and 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 .

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1 European Medicines Agency. Herceptin Summary of Product Characteristics. Available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000278/WC500074922.pdf. Accessed November 2017. 2 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. 3 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 4 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. 5 Macmillan. HER2 positive breast cancer. Available at https://www.macmillan.org.uk/cancerinformation/cancertypes/breast/aboutbreastcancer/typesa 6 Iqbal N, Iqbal N. Human Epidermal Growth Factor Receptor 2 (HER2) in Cancers: Overexpression and Therapeutic Implications. Mol Biol Int. 2014. 10.1155/2014/852748. Pfizer. (2018, January 30). Pfizer pipeline. Retrieved from https://www.pfizer.com/sites/default/files/product-pipeline/01302018_PipelineUpdate.pdf. 7 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/hum Accessed May 2018. 8 European Medicines Agency. European public assessment report (EPAR) for INFLECTRA. Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002778/hum Accessed May 2018. 9 European Medicines Agency. European public assessment report (EPAR) for NIVESTIM. Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001142/hum

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