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Pfizer Provides Update on Proposed Trastuzumab Biosimilar

Monday, April 23, 2018 - 03:45am

Pfizer Inc. (NYSE:PFE) today announced that it received a Complete Response Letter (CRL) from the United States Food and Drug Administration (FDA) in response to the Biologics License Application for the company's proposed trastuzumab biosimilar. In the CRL, the FDA highlighted the need for additional technical information. The additional requested information does not relate to safety or clinical data submitted in the application. Pfizer is working closely with the FDA to address the contents of the letter and remains committed to bringing this important medicine to patients in the U.S.

Pfizer believes that biosimilars are critically important to the future of cancer care, with the potential to increase patient access to life-changing therapies that will help address the evolving needs of healthcare systems, patients, physicians and payers.

Pfizer Inc.: 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 April 23, 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 Pfizer's proposed trastuzumab biosimilar, 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, the uncertainties inherent in research and development, including the ability to meet anticipated 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; uncertainties regarding the company's ability to address the comments in the complete response letter to the satisfaction of the FDA; whether and when any applications for Pfizer's proposed trastuzumab biosimilar may be filed with regulatory authorities in any other jurisdictions; whether and when the FDA may approve the biologics license application for Pfizer's proposed trastuzumab biosimilar and whether and when regulatory

authorities in any other jurisdictions may approve any such other applications that are pending or that may be filed for Pfizer's proposed trastuzumab biosimilar, 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 Pfizer's proposed trastuzumab biosimilar 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 Pfizer's proposed trastuzumab biosimilar ; 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, 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 10-Q and 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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