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Pfizer Provides Update on Proposed Epoetin Alfa Biosimilar

NEW YORK, N.Y., June 22 – Pfizer Inc. (NYSE:PFE) today announced that it has received a Complete Response Letter (CRL) from the United States (U.S.) Food and Drug Administration (FDA) regarding the company's Biologics License Application (BLA) for its proposed epoetin alfa biosimilar. This CRL relates to matters noted in a Warning Letter issued on February 14, 2017 following a routine Agency inspection of the company's facility in McPherson, Kansas in 2016. This facility was listed as the potential manufacturing site in the BLA for the proposed epoetin alfa biosimilar. The issues noted in the Warning Letter do not relate specifically to the manufacture of epoetin alfa.

No additional clinical data was requested in the CRL at this time to support a future approval.

An Oncologic Drugs Advisory Committee (ODAC) voted on May 25, 2017 to recommend this proposed biosimilar for approval. The ODAC's recommendation was based, in part, on the FDA's briefing materials, which concluded that proposed biosimilar epoetin alfa is highly similar to its reference product, Epogen® and Procrit® (epoetin alfa)[1], and supports a demonstration that there are no clinically meaningful differences in terms of the safety, purity and potency of the product[2].

Pfizer submitted a corrective and preventative action plan to the FDA in March 2017, and has been diligently working to address the

items outlined in the Warning Letter. Pfizer provides regular updates to FDA on the status of its action plan, and remains dedicated to addressing all of FDA's concerns with the McPherson, KS site.

The company is committed to making this important treatment option available to patients and physicians as quickly as possible.

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 @PfizerNews, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of June 22, 2017. 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 epoetin alfa 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 and warning letter to the satisfaction of the FDA; whether and when any applications for biosimilar epoetin alfa or any other biosimilars in development may be filed with regulatory authorities in any jurisdictions; whether and when the FDA or regulatory authorities in any other jurisdictions may approve any applications for biosimilar epoetin alfa or any other biosimilars in development, 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; intellectual property and/or litigation implications; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of biosimilar epoetin alfa or any other biosimilars in development; 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, 2016 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] Epogen® is a registered U.S. trademark of Amgen Inc.; Procrit® is a registered U.S. trademark of Johnson & Johnson.

[2] U.S. Food & Drug Administration, Oncologic Drugs Advisory Committee Meeting. (2017, May 23). ODAC Briefing Document: BLA 125545 for "Epoetin Hospira", a proposed biosimilar to Epogen/Procrit. Retrieved from https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM559967.pdf.