FDA Advisory Committee Recommends Approval of Pfizer’s Proposed Biosimilar to Epogen®/Procrit® Across All Indications

Thursday, May 25, 2017 - 09:16am

“The Committee’s recommendation reinforces the potential value of biosimilars in expanding access to additional high-quality treatment options for the patients in the U.S. who need them.”

Pfizer Inc. (NYSE:PFE) today announced the United States (U.S.) Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC) recommended approval of the Company’s proposed epoetin alfa biosimilar across all indications. This marks the first time a biosimilar erythropoiesis-stimulating agent (ESA) has been recommended for approval by a U.S. FDA Advisory Committee.

The Committee’s favorable recommendation was based on its review of the totality of evidence, including demonstration of comparable efficacy and safety of biosimilar epoetin alfa to its reference product, Epogen® and Procrit® (epoetin alfa).[1]

The company is seeking FDA approval of the following indications:

•Treatment of anemia due to:

o Chronic Kidney Disease (CKD) in patients on dialysis and not on dialysis.

o Zidovudine in HIV-infected patients.

o The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.

•Reduction of allogeneic red blood cell (RBC) transfusions in patients undergoing elective, noncardiac, nonvascular surgery.

“The Committee’s recommendation reinforces the potential value of biosimilars in expanding access to additional high-quality treatment options for the patients in the U.S. who need them,” said Diem Nguyen, Global President, Americas, Pfizer Essential Health. “Following the approval and launch of INFLECTRA® (infliximab-dyyb) in 2016, this positive recommendation – a first for a proposed ESA biosimilar – marks an important milestone for Pfizer’s U.S. biosimilars portfolio.”

The FDA will take the Committee’s recommendation into consideration before taking action on the Biologics License Application (BLA) for the proposed epoetin alfa biosimilar across all indications.

Pfizer has entered into an agreement with Vifor Pharma Inc. for the commercialization of its proposed epoetin alfa biosimilar in certain channels.

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 May 25, 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; 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 regulatory authorities in any such jurisdictions may approve any such 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.

---

[1] Epogen® is a registered U.S. trademark of Amgen Inc.; Procrit® is a registered U.S. trademark of Johnson & Johnson

Media: Rachel Hooper M: +1 916-708-1868 Rachel.Hooper@pfizer.com or Investor: Ryan Crowe O: +1 212-733-8160 Ryan.Crowe@pfizer.com