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Pfizer Presents Positive 26-Week Data For PF-05280586, A Potential Biosimilar To Rituximab, At The American Society Of Hematology Annual Meeting

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26-week data from the ongoing 52-week REFLECTIONS B328-06 study met its primary endpoint, demonstrating comparable safety and efficacy for patients with indolent follicular lymphoma The U.S. Food and Drug Administration (FDA) accepted for review, a Biologics License Application (BLA) for PF-05280586 in September 2018

Pfizer Inc. (NYSE:PFE) announced today at the American Society of Hematology Annual Meeting that the REFLECTIONS B328-06 study, a comparative safety and efficacy study of PF-05280586 versus Rituxan® /MabThera® (rituximab-EU)[i], met its primary endpoint of overall response rate (ORR) at Week 26 of the 52-week study.[1]

“It is encouraging to see new data supporting a potential rituximab Biosimilar. If approved this may help provide a more cost-effective treatment option and expand access for patients and physicians,” said Dr. Jeff Sharman, medical director, US Oncology Hematology Research. “The data presented today will help us understand the nuances of the medicine without the confounding influence of additional concurrent treatments.”

26-week data from the ongoing 52-week REFLECTIONS B328-06 study (n=394) demonstrated no clinically meaningful differences in efficacy, in terms of ORR at Week 26, between PF-05280586 and MabThera, for the first-line treatment of patients with CD20-positive, low tumor burden, follicular lymphoma (LTB-FL).[1] ORR at Week 26 was 75.5% (PF-05280586) vs 70.7% (rituximab-EU), and was within the pre-specified equivalence margin. ORR is defined as the percentage of patients achieving complete response (CR) or partial response (PR), based on central review. Additionally, estimated rates of one-year progression-free survival were similar across groups (76.4% vs. 81.2% in the PF-05280586 and MabThera groups, respectively).[1] The results also show that PF-05280586 had a similar safety profile to MabThera.[1]

“With a patient centered approach and over a decade of experience globally,[2] Pfizer remains dedicated to developing and delivering high quality biosimilars with similar efficacy and safety profiles to originator medicines that help have a meaningful impact on people living with various conditions including cancer,” said Joe McClellan, vice president, Biosimilars Development at Pfizer. “We have also been a committed global partner to the oncology community for almost 20 years, and the continued growth of our oncology and supportive care presence, through both novel therapies and biosimilars, means we are able to provide patients, physicians and healthcare systems with a wider range of treatment options.”

PF-05280586 has been accepted for review by the FDA, the BsUFA goal date for a decision by the FDA is in second-quarter 2019. Pfizer is also working towards making PF-05280586 available for patients in Europe.

Further results on the safety and efficacy from this ongoing 52-week study in LTB-FL are expected to be presented next year.

About PF-05280586

PF-05280586 is a monoclonal antibody (mAb) that is in development as a potential biosimilar to Rituxan/MabThera. Rituxan/MabThera is indicated for the treatment of patients with certain types of CD20-positive non-Hodgkin lymphoma; CD20-positive chronic lymphocytic leukemia; rheumatoid arthritis; granulomatosis with polyangiitis and microscopic polyangiitis; and other region-specific indications.[3], [4]

PF-05280586 is an investigational compound and has not received regulatory approval in any country. Biosimilarity has not yet been established by regulatory authorities.

About the REFLECTIONS B328-06 Study

REFLECTIONS B328-06 is a randomized, 52-week double-blind clinical trial evaluating the efficacy, safety and immunogenicity, pharmacokinetics and pharmodynamics of PF-05280586 versus MabThera for the first-line treatment of patients with CD20-positive, low tumor burden, follicular lymphoma.

More information about the PF-05280586 REFLECTIONS B32806 study can be found at www.clinicaltrials.gov .

About Pfizer: 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 or 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 December 2, 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 a product candidate, PF-05280586, 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 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 new drug

applications may be filed in any jurisdictions for PF-05280586; whether and when any such applications 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 PF-05280586 will be commercially successful; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of PF-05280586; 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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[i] Rituximab is marketed in the U.S. under the brand name Rituxan® and marketed in the E.U. and other regions under the brand name MabThera®. Rituxan® and MabThera® are registered trademarks of Genentech, Inc.

[1] Sharman, J et al. A Randomized, Double-Blind Efficacy and Safety Study of PF-05280586 (a Potential Rituximab Biosimilar) Compared with Rituximab Reference Product (MabThera®) in Subjects with Previously Untreated CD20-Positive, Low Tumor Burden Follicular Lymphoma (LTB-FL). ASH 2018. Available at https://ash.confex.com/ash/2018/webprogram/Paper111248.html. Accessed November 2018.

[2] EMA Product Information for RETACRIT. Available at: https://www.ema.europa.eu/medicines/human/EPAR/retacrit. Accessed November 2018.

[3] FDA Prescribing Information for RITUXAN. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103705s5367s5388lbl.pdf. Accessed November 2018.

[4] EMA Product Information for MABTHERA. Available at: https://www.ema.europa.eu/medicines/human/EPAR/mabthera#product-information-section. Accessed November 2018.

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