Pfizer Receives Positive CHMP Opinion for Oncology Biosimilar, RUXIENCE™ (rituximab)

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NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion, recommending marketing authorization for RUXIENCE™ (rituximab),1 a potential biosimilar to MabThera® (rituximab).2,3 RUXIENCE is a monoclonal antibody (mAb) for the treatment of non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL), rheumatoid arthritis (RA), granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA), and pemphigus vulgaris (PV).1 The CHMP's opinion will now be reviewed by the European Commission, with a regulatory decision anticipated in the first half of 2020.

"Biosimilars like RUXIENCE can play an important role in cancer care, helping to expand patient access to potentially life-changing therapies," said Chris Boshoff, M.D., Ph.D., Chief Development Officer, Oncology, Pfizer Global Product Development. "We are committed to bringing biosimilars like RUXIENCE to the market as a treatment option with similar safety and efficacy to the originator product at a potentially lower cost. If approved, RUXIENCE would become Pfizer's fifth oncology biosimilar to receive regulatory approval in Europe."

The regulatory submission is supported by a comprehensive data package which demonstrates biosimilarity of RUXIENCE to the reference product. This includes results from the REFLECTIONS B3281006 clinical comparative study, which evaluated the efficacy, safety and immunogenicity, pharmacokinetics and pharmacodynamics of RUXIENCE and found no clinically meaningful differences in safety or efficacy compared to the reference product in patients with CD20-positive, low tumor burden follicular

lymphoma.4

Biosimilars have been a significant catalyst for change for the healthcare industry over the last decade, with the potential to help create a more sustainable healthcare system. With more than 10 years of global in-market experience and five approved biosimilar products in Europe, Pfizer is proud to be a leader and at the forefront of this vital healthcare segment. RUXIENCE was also approved for use in the United States for the treatment of adult patients with NHL, CLL, GPA and MPA in 2019 and was recently made available to U.S. patients.

About Pfizer Oncology

At Pfizer Oncology, we are committed to advancing medicines wherever we believe we can make a meaningful difference in the lives of patients. Today, Pfizer Oncology has an industry-leading portfolio of 22 approved innovative cancer medicines and biosimilars across more than 30 indications, including breast, prostate, kidney and lung cancers, as well as leukemia and melanoma. Pfizer Oncology is striving to change the trajectory of cancer.

Pfizer Inc.: Breakthroughs that change patients' lives®

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, including innovative medicines and vaccines. 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 January 31, 2020. 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 RUXIENCE (rituximab), 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, uncertainties regarding the launch timing and commercial success of RUXIENCE in the EU; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when applications for RUXIENCE may be filed in any other jurisdictions; whether and when the European Medicines Agency will approve the pending application and whether and when regulatory authorities in any other jurisdictions may approve any such other applications for RUXIENCE that may be pending or filed, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether RUXIENCE will be commercially successful; intellectual property and/or litigation implications; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of RUXIENCE; uncertainties regarding access challenges for our biosimilar products where our product may not receive appropriate formulary access or remains in a disadvantaged position relative to the innovator product; 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, 2018 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. RUXIENCE Summary of Opinion. Available at https://www.ema.europa.eu/en/medicines/human/summaries-opinion/ruxience. Accessed January 2020. 2 MabThera® is a registered trademark of Roche, Inc. 3 European Medicines Agency. MabThera EPAR Summary for the Public. Available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-

_Summary_for_the_public/human/000165/WC500025815.pdf. Accessed January 2020 4 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). BioDrugs. 2019. Doi:10.1007/s40259-019-00398-7

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