Gilead Submits Filgotinib New Drug Application to U.S. Food and Drug Administration Under Priority Review for Rheumatoid Arthritis Treatment

December 19, 2019

FOSTER CITY, Calif.--(BUSINESS WIRE)--Dec. 19, 2019-- Gilead Sciences, Inc. (NASDAQ: GILD) announced today that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for filgotinib, an investigational, oral, selective JAK1 inhibitor for the treatment of adults who are living with moderate-to-severe rheumatoid arthritis (RA). A priority review voucher was submitted with the NDA, shortening the anticipated time for review.

The filing is supported by 52-week data from the global Phase 3 FINCH clinical program, which evaluated the efficacy and safety of filgotinib in 3,452 patients with moderate to severely active RA. In the FINCH studies, filgotinib met its primary endpoints and demonstrated durable efficacy and safety results across multiple RA patient populations, including in people with prior inadequate response to methotrexate treatment (MTX), those who were intolerant to one or more biologic treatments and those who were MTX treatment-naïve. Safety results were consistent across the trials and further reinforce the long-term safety and tolerability profile of filgotinib for a broad range of RA patients.

Despite the availability of current therapies, people living with RA may face persistent disease symptoms and inadequate responses to currently available therapies. One in five patients do not achieve complete disease remission during their lifetimes and remain in need of treatment options.

“The new drug application submission for filgotinib represents an important step forward in bringing a potential new treatment option to people living with RA,” said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. “In clinical trials, filgotinib has demonstrated an efficacy and tolerability profile that may offer meaningful improvements in RA treatment response for patients with this chronic, debilitating disease.”

This filing is the third regulatory agency submission for filgotinib in the past five months following submissions to the European Medicines Agency and Japanese Ministry of Health, Labor and Welfare earlier this year.

Filgotinib is an investigational agent and is not approved by any regulatory authority. Its efficacy and safety have not been established.

About the Filgotinib Collaboration[i]

Gilead and Galapagos NV are collaborative partners in the global development and commercialization of filgotinib in RA, and other potential inflammatory indications. In the United States, Gilead is solely responsible for the commercialization of filgotinib, pending approval of filgotinib by the FDA.

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California. For more information on Gilead Sciences, please visit the company’s website at www.gilead.com.

Gilead Forward-Looking Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the possibility of unfavorable results from ongoing and additional clinical trials involving filgotinib and the possibility that we may be unable to complete one or more of such trials in the currently anticipated timelines or at all. Further, it is possible that the parties may make a strategic decision to discontinue development of filgotinib, and as a result, filgotinib may never be successfully commercialized. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

For more information on Gilead Sciences, please visit the company’s website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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[i] Gilead & Galapagos Filgotinib Clinical Program Trial Details: SELECTION (NCT02914522); DIVERSITY (NCT02914561); PENGUIN 1 (NCT04115748); PENGUIN 2 (NCT04115839)

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