



Gilead Announces Intent to Submit New Drug Application for Filgotinib to U.S. Food and Drug Administration This Year

July 1, 2019

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jul. 1, 2019-- Gilead Sciences, Inc. (NASDAQ: GILD) today announced that at a recent pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA), the company provided an update about the investigational, oral, selective JAK1 inhibitor filgotinib. The company discussed with the agency the Phase 3 FINCH studies, as well as the ongoing Phase 2 MANTA safety study assessing semen parameters with filgotinib treatment in men with moderately to severely active ulcerative colitis or Crohn's disease. As a result of this discussion, a path forward has been established to submit the NDA for filgotinib as a treatment for rheumatoid arthritis in 2019.

Filgotinib is an investigational agent and not approved anywhere globally. Its efficacy and safety have not been established.

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, the possibility that the company is unable to file the filgotinib NDA on the currently anticipated timelines and the possibility that the FDA could refuse to approve filgotinib or significantly delay approval. 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 March 31, 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 about Gilead, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@Gilead Sciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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