EUROPEAN MEDICINES AGENCY VALIDATES MARKETING APPLICATION FOR FILGOTINIB FOR THE TREATMENT OF ULCERATIVE COLITIS

-- Application Based on Results from Pivotal Phase 2b/3 SELECTION Trial --

Foster City, Calif., & Mechelen, Belgium, November 2, 2020, 22.01 CET – Gilead Sciences, Inc. (Nasdaq: GILD) and Galapagos NV (Euronext & Nasdaq: GLPG) today announced that the application for a new indication to the approved license for filgotinib 200 mg, an oral JAK1 preferential inhibitor, has been validated and is now under evaluation by the European Medicines Agency (EMA). The proposed indication is for the treatment of adults with moderately to severely active ulcerative colitis (UC) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent.

Ulcerative colitis is a long term, chronic condition which affects more than 2 million people in the European Union alone. Symptoms tend to present intermittently, and so patients usually experience flare-ups and periods of remission. The EMA application is supported by data from the Phase 2b/3 SELECTION study, which showed a statistically significantly higher proportion of patients treated with once-daily, oral, filgotinib 200 mg achieved clinical remission at week 10 and maintained remission at week 58 compared with placebo. Additionally, a statistically significantly higher proportion of patients treated with filgotinib 200 mg achieved endoscopic, histologic and six-month, corticosteroid-free remission at week 58 compared with placebo. The SELECTION trial results were presented at the virtual United European Gastroenterology Week (UEGW) 2020 Meeting last month.

“Today’s news from the EMA is a welcome step forward in our work aiming to improve outcomes for people living with inflammatory diseases, many of whom struggle with ongoing symptoms and are in need of new treatment options,” said Mark Genovese, MD, Senior Vice President, Inflammation, Gilead Sciences.

“We are very pleased to have achieved this important milestone with filgotinib, building on its recent regulatory approvals in rheumatoid arthritis in the EU and Japan, as we bring this potential new treatment option one step closer for people living with UC,” said Dr. Walid Abi-Saab, Chief Medical Officer, Galapagos.

Initiating assessment of the application begins the formal evaluation process by the EMA’s Committee for Human Medicinal Products (CHMP). The filing will be reviewed under the centralized licensing procedure for all 27 member states of the European Union, as well as Norway, Iceland and Liechtenstein. Filgotinib is already licensed in the European Union as Jyseleca®▼ for the treatment of patients with moderate to severe active rheumatoid arthritis (RA) who have responded inadequately or are intolerant to one or more disease modifying anti-rheumatic drugs (DMARDs). The use of filgotinib for UC is investigational and is not approved anywhere globally.

About the SELECTION Phase 2b/3 Trial

The SELECTION Phase 2b/3 trial is a multi-center, randomized, double-blind, placebo-controlled trial that demonstrated sustained efficacy and safety with filgotinib for the treatment of moderately to severely active UC. The SELECTION studies tested 100 mg and 200 mg filgotinib versus placebo in bio-naïve and bio-experienced moderate to severe UC populations, the bio-experienced populations included more than 50% of UC patients who had experienced two different mode of action biologics. The SELECTION trial demonstrated that a statistically significantly higher proportion of patients treated with filgotinib 200 mg

versus placebo achieved clinical remission at week 10 and maintained remission at week 58. In addition, statistically significantly more patients achieved six-month corticosteroid-free remission. Overall, the incidence of adverse events (AEs), serious AEs and discontinuations due to AEs were similar in the filgotinib and placebo groups in both the induction and maintenance periods of the study. Serious infections, herpes zoster, venous thrombosis, pulmonary embolism and gastrointestinal perforation were similar across treatment groups.

About Filgotinib

Filgotinib (200 mg and 100 mg tablets) is approved and marketed as Jyseleca® in Europe and Japan for the treatment of adults with moderately to severely active RA who have responded inadequately or are intolerant to one or more disease modifying anti-rheumatic drugs (DMARDs)**.** Jyseleca® may be used as monotherapy or in combination with methotrexate (MTX). The full European Summary of Product Characteristics for filgotinib is available from the EMA at www.ema.europa.eu, and the interview form from the Japanese Ministry of Health, Labour and Welfare (MHLW) is available at www.info.pmda.go.jp.

About the Filgotinib Collaboration

Gilead and Galapagos NV are collaborative partners in the global development of filgotinib in RA, inflammatory bowel disease and other inflammatory indications. The companies are conducting global studies investigating the potential role of filgotinib in a variety of diseases, including the Phase 3 DIVERSITY trial in Crohn's disease.

More information about clinical trials with filgotinib can be accessed at: www.clinicaltrials.gov.

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.

About Galapagos

Galapagos NV discovers and develops small molecule medicines with novel modes of action, several of which show promising patient results and are currently in late-stage development in multiple diseases. Our pipeline comprises discovery through Phase 3 programs in inflammation, fibrosis and other indications. Our ambition is to become a leading global biopharmaceutical company focused on the discovery, development and commercialization of innovative medicines. More information at www.glpg.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. There is also the possibility of unfavorable results from ongoing and additional clinical trials involving filgotinib, including the SELECTION long-term extension trial and the DIVERSITY trial. Further, it is possible that the parties may make a strategic decision to discontinue development of filgotinib for the treatment of ulcerative colitis or other indications, and as a result, filgotinib may never be successfully commercialized for the treatment of ulcerative colitis or other indications. 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 Form 10-Q for the quarter ended June 30, 2020, 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.

Galapagos Forward-Looking Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, that are subject to risks, uncertainties and other factors that could cause actual results to differ materially from those referred to in the forward-looking statements and, therefore, the reader should not place undue reliance on them. These risks, uncertainties and other factors include, without limitation, the inherent risks associated with clinical trial and product development activities, competitive developments, and regulatory approval requirements, including the risk that data from the ongoing and planned clinical research programs with filgotinib may not support registration or further development for ulcerative colitis or other indications due to safety, efficacy or other reasons, the timing or likelihood of regulatory authorities' approval of marketing authorization for filgotinib for ulcerative colitis or other indications, such regulatory authorities requiring additional studies, Galapagos' reliance on collaborations with third parties, including the collaboration with Gilead for filgotinib, the uncertainty regarding estimates of the commercial potential of filgotinib, as well as those risks and uncertainties identified in our Annual Report on Form 20-F for the year ended 31 December 2019 and our subsequent filings with the SEC. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The forward-looking statements contained herein are based on management's current expectations and beliefs and speak only as of the date hereof, and Galapagos makes no commitment to update or publicly release any revisions to forward-looking statements in order to reflect new information or subsequent events, circumstances or changes in expectations.

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