GILEAD AND GALAPAGOS ANNOUNCE POSITIVE EUROPEAN CHMP OPINION FOR JYSELECA® (FILGOTINIB) FOR THE TREATMENT OF ADULTS WITH MODERATE TO SEVERE RHEUMATOID ARTHRITIS

-- Clinical Development Program of Filgotinib Demonstrated Durable Efficacy Balanced with a Consistent Safety Profile in Rheumatoid Arthritis Through 52 Weeks --

Foster City, Calif., and Mechelen, Belgium, July 24 2020, 14:10 CET; regulated information – Gilead Sciences, Inc. (Nasdaq: GILD) and Galapagos NV (Euronext & Nasdaq: GLPG) announced today the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for Jyseleca® (filgotinib 200 mg and 100 mg tablets), an investigational, once-daily, oral, selective JAK1 inhibitor for the treatment of adults with moderate to severe rheumatoid arthritis (RA) who have responded inadequately or are intolerant to one or more disease modifying anti-rheumatic drugs (DMARDs). The CHMP positive opinion is a scientific recommendation to the European Commission to grant marketing authorization in Europe.

The CHMP positive opinion is supported by data from the Phase 3 FINCH and Phase 2 DARWIN programs, which included 4,544 RA patient-years of experience with filgotinib. All three FINCH trials, involving a broad range of patients, met their primary endpoints. In the trials, filgotinib consistently achieved ACR20/50/70 and other relevant treatment targets, such as DAS28(CRP)<2.6. Filgotinib also inhibited the progression of structural joint damage assessed by modified total Sharp score (mTSS) compared with placebo. Across the FINCH and DARWIN trials, once-daily filgotinib demonstrated a consistent clinical safety profile when administered as monotherapy or in combination with methotrexate (MTX). Rates of serious infections and herpes zoster were generally similar to adalimumab and MTX, while rates of major adverse cardiac events (MACE) and venous thromboembolism (VTE) were infrequently reported.

The CHMP positive opinion will now be reviewed by the European Commission, which has the authority to authorize medicines in the 27 countries of the European Union, Norway, Iceland, Liechtenstein and UK. A Commission decision is expected in the third quarter of 2020.

Filgotinib is an investigational agent and is not approved for use by any regulatory authority.

About the FINCH Program
The FINCH Phase 3 program investigated the efficacy and safety of filgotinib 100 mg and 200 mg once-daily, in RA patient populations ranging from early stage to biologic-experienced patients. FINCH 1 was a 52-week, randomized, placebo- and adalimumab-controlled trial in combination with MTX, enrolling 1,759 adult patients with moderately to severely active RA who had inadequate response to MTX. The primary endpoint in FINCH 1 was ACR20 at Week 12. The trial included radiographic assessment at Weeks 24 and 52. FINCH 2 was a global, 24-week randomized, double-blind, placebo-controlled, Phase 3 study evaluating filgotinib on a background of conventional synthetic disease-modifying anti-rheumatic drug(s) (csDMARDs) among 449 adult patients with moderately to severely active RA who had not adequately responded to biologic DMARDs (bDMARDs). The primary endpoint in FINCH 2 was ACR20 at Week 12. FINCH 3 was a 52-week, randomized trial in 1,252 MTX-naïve patients to evaluate filgotinib 200 mg alone
and filgotinib 100 mg or 200 mg combined with MTX versus MTX alone in MTX-naïve patients. The primary endpoint in FINCH 3 was ACR20 at Week 24. The trial included radiographic assessment at Weeks 24 and 52. Filgotinib is an oral, selective JAK inhibitor with preferential activity for JAK1 and JAK 1/3 signaling.

**About the Filgotinib Collaboration**
Gilead and Galapagos NV are collaborative partners in the global development and commercialization of filgotinib in RA and other inflammatory indications. The companies have multiple clinical study programs for filgotinib in inflammatory diseases, including the FINCH Phase 3 program in RA, the Phase 3 SELECTION trial in ulcerative colitis, the DIVERSITY Phase 3 trial in Crohn’s disease, the Phase 3 PENGUIN trials in psoriatic arthritis, as well as Phase 2 studies in uveitis and in small bowel and fistulizing Crohn’s disease.

More information about clinical trials with filgotinib can be accessed at: [www.clinicaltrials.gov](http://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](http://www.gilead.com).

**About Galapagos**
Galapagos NV discovers and develops small molecule medicines with novel modes of action, three 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, osteoarthritis 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](http://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, including the risk that the European Commission may not approve filgotinib for the treatment of adults with moderate to severe rheumatoid arthritis in the expected timelines or at all. There is also the possibility of unfavorable results from ongoing and additional clinical trials involving filgotinib. 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 Form 10-Q for the quarter ended March 31, 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 uncertainties associated with competitive developments, clinical trial and product development activities, and regulatory approval requirements (including that data from the ongoing and planned clinical research programs with filgotinib may not support registration or further development of filgotinib due to safety, efficacy or other reasons), whether or when regulatory authorities would approve marketing authorization for filgotinib, Galapagos' reliance on collaborations with third parties (including its collaboration partner for filgotinib, Gilead), the uncertainty regarding estimating 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 December 31, 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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