



## Gilead and Galapagos Announce Filgotinib Meets Primary and Key Secondary Endpoints in the Phase 3 FINCH 1 Rheumatoid Arthritis Study

March 28, 2019

**-- Filgotinib 100 mg and 200 mg Doses Demonstrated Significantly Higher ACR20/50/70 Responses than Placebo in Patients with Prior Inadequate Methotrexate Response --**

**-- Significant Inhibition of Radiographic Progression Demonstrated with Both Doses of Filgotinib versus Placebo --**

**-- Safety Profile of Filgotinib Consistent with Previously Reported Results --**

FOSTER CITY, Calif. & MECHELEN, Belgium--(BUSINESS WIRE)--Mar. 28, 2019-- regulated information – Gilead Sciences, Inc. (NASDAQ: GILD) and Galapagos NV (Euronext & NASDAQ: GLPG) today announced Week 24 results of FINCH 1, an ongoing, randomized, double-blind, placebo- and active-controlled Phase 3 study of filgotinib, an investigational, oral, selective JAK1 inhibitor, in adults with moderately-to-severely active rheumatoid arthritis. FINCH 1 evaluated filgotinib versus adalimumab or placebo, on a stable background dose of methotrexate in patients with prior inadequate response to methotrexate. The study achieved its primary endpoint for both doses of filgotinib in the proportion of patients achieving an American College of Rheumatology 20 percent response (ACR20) compared to placebo at Week 12.

The proportion of patients achieving ACR50 and ACR70 response was also significantly greater for filgotinib compared with placebo at Week 12, for both doses. Patients receiving filgotinib 100 mg or 200 mg had a statistically significant reduction in the Health Assessment Questionnaire Disability Index (HAQ-DI) at Week 12 compared with those receiving placebo. The proportions of patients achieving clinical remission (DAS28(CRP) < 2.6) and low disease activity (DAS28(CRP) ≤ 3.2) at Week 12 were significantly higher for patients in both filgotinib arms compared with placebo. When comparing low disease activity rates at Week 12, filgotinib 200 mg was non-inferior to adalimumab. Filgotinib 100 mg and 200 mg also significantly inhibited the progression of structural damage at Week 24 as assessed by change from baseline in modified total Sharp score (mTSS) compared with placebo.

Top-line FINCH 1 efficacy† data are summarized in the table below.

|  | Filgotinib<br>200 mg<br>+MTX<br>(n=475)& | Filgotinib<br>100 mg<br>+MTX<br>(n=480)& | Adalimumab 40 mg<br>+MTX<br>(n=325)& | Placebo<br>+MTX<br>(n=475)& |
|--|--|--|--------------------------------------|-----------------------------|
| ACR20 (%)                                      | 76.6***                                  | 69.8***                                  | 70.8                                 | 49.9                        |
| ACR50 (%)                                      | 47.2***                                  | 36.3***                                  | 35.1                                 | 19.8                        |
| ACR70 (%)                                      | 26.3***                                  | 18.5***                                  | 14.2                                 | 6.7                         |
| DAS28(CRP) ≤ 3.2<br>(Low disease activity) (%) | 49.7***\$                                | 38.8***                                  | 43.4                                 | 23.4                        |
| DAS28(CRP) < 2.6<br>(Clinical remission) (%)   | 33.9*** ¥#                               | 23.8*** £#                               | 23.7                                 | 9.3                         |
| HAQ-DI change                                  | -0.69***                                 | -0.56***                                 | -0.61                                | -0.42                       |
| mTSS change                                    | 0.13***                                  | 0.17***                                  | 0.16                                 | 0.38                        |

†All efficacy time points assessed at Week 12 except mTSS which was assessed at Week 24

&Number of patients randomized to each treatment group and who received at least one dose of study drug

ACR20/50/70 represents American College of Rheumatology 20%/50%/70% improvements.

\*\*\* p < 0.001, compared with placebo

\$ p < 0.001, non-inferiority to adalimumab

£ p < 0.01, non-inferiority to adalimumab

¥ p < 0.01, superiority to adalimumab

# Comparison not adjusted for multiplicity

The safety profile of filgotinib in FINCH 1 is consistent with prior studies up to Week 24. Serious adverse events occurred in 4.4 percent, 5.0 percent, 4.3 percent and 4.2 percent of the patients in the filgotinib 200 mg, filgotinib 100 mg, adalimumab and placebo groups, respectively. There were five deaths, two patients were assigned to the placebo group, two to the filgotinib 200 mg group and one to the filgotinib 100 mg group. Five patients with a malignancy were also reported -- three receiving placebo, one receiving adalimumab and one receiving filgotinib 100 mg, respectively. Three venous thrombotic events were observed (two in the placebo group, one in the filgotinib 200 mg group), and there were four adjudicated major adverse cardiovascular events, two in the placebo, one in the adalimumab and one in the filgotinib 100 mg groups. The proportion of patients with herpes zoster was similar across treatment groups (filgotinib 200 mg = 0.4 percent, filgotinib 100 mg = 0.4 percent, adalimumab = 0.6 percent, placebo = 0.4

percent), as was the rate of serious infections (filgotinib 200 mg = 1.7 percent, filgotinib 100 mg = 1.7 percent, adalimumab = 2.5 percent, placebo = 0.8 percent).

“These FINCH 1 data add to the favorable results obtained previously in the FINCH 2 study in patients with a prior inadequate response to biologic agents and reinforce the evidence supporting the potential of filgotinib to address unmet treatment needs in patients with rheumatoid arthritis,” said John McHutchison, AO, MD, Chief Scientific Officer, Head of Research and Development, Gilead Sciences. “Across the FINCH program, the data continue to support filgotinib’s potential as a JAK1 specific inhibitor that may provide clinically meaningful responses combined with a favorable safety profile in a wide range of people living with rheumatoid arthritis, including those in the early stages of disease and those who have tried standard therapies without success.”

“Many patients living with rheumatoid arthritis are in need of new treatment options that are effective, well-tolerated, and convenient. We are excited about the strong efficacy and tolerability results with both doses of filgotinib,” said Dr. Walid Abi-Saab, Chief Medical Officer, Galapagos. “We are particularly pleased with the results filgotinib shows on clinically meaningful endpoints such as clinical remission, ACR70 and radiographic progression, as well as with the encouraging safety profile.”

Detailed findings from FINCH 1 will be submitted for presentation at a future scientific conference. Filgotinib is an investigational agent and not approved anywhere globally. Its efficacy and safety have not been established.

### **About FINCH 1**

FINCH 1 is an ongoing 52-week randomized, double-blind, placebo- and active-controlled study, enrolling 1,759 adult patients with moderately to severely active RA who have an inadequate response to MTX. Eligible patients were randomized (3:3:2:3) to receive filgotinib 200 mg (n=477), filgotinib 100 mg (n=480), adalimumab (n=325) or placebo (n=477) in addition to a stable dose of MTX. The primary endpoint of the study is the proportion of patients who achieve an American College of Rheumatology 20 percent improvement response (ACR20) at Week 12. At Week 24, all patients in the placebo arm who did not discontinue study drug were reassigned (1:1) to either filgotinib 100 mg or 200 mg.

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

### **About the Galapagos – Gilead Collaboration**

Galapagos and Gilead entered into a global collaboration for the development and commercialization of filgotinib in inflammatory indications. The FINCH studies are among several clinical trials of filgotinib in inflammatory diseases, including the EQUATOR Phase 2 program in psoriatic arthritis, the TORTUGA study in ankylosing spondylitis, the DIVERSITY Phase 3 trial in Crohn’s disease (also small bowel and fistulizing Crohn’s disease Phase 2 studies) and the Phase 3 SELECTION trial in ulcerative colitis.

### **About Galapagos**

Galapagos (Euronext & NASDAQ: GLPG) 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 Phase 3 through to discovery 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).

*This press release contains inside information within the meaning of Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (market abuse regulation).*

### **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).

### **Galapagos Forward-Looking Statements**

This release may contain forward-looking statements with respect to Galapagos, including statements regarding Galapagos’ strategic ambitions, the mechanism of action and potential safety and efficacy of filgotinib, the anticipated timing of clinical studies with filgotinib and the progression and results of such studies. Galapagos cautions the reader that forward-looking statements are not guarantees of future performance. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition and liquidity, performance or achievements of Galapagos, or industry results, to be materially different from any historic or future results, financial conditions and liquidity, performance or achievements expressed or implied by such forward-looking statements. In addition, even if Galapagos’ results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. Among the factors that may result in differences are 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 may not support registration or further development of filgotinib due to safety, efficacy or other reasons), Galapagos’ reliance on collaborations with third parties (including its collaboration partner for filgotinib, Gilead), and estimating the commercial potential of Galapagos’ product candidates. A further list and description of these risks, uncertainties and other risks can be found in Galapagos’ Securities and Exchange Commission (SEC) filings and reports, including in Galapagos’ most recent annual report on form 20-F filed with the SEC and subsequent filings and reports filed by Galapagos with the SEC. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. Galapagos expressly disclaims any obligation to update any such forward-looking statements in this document to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements, unless specifically required by law or regulation.

### **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. 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 Annual Report on Form 10-K for the year ended December 31, 2018, 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.

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