



## Gilead and Galapagos Announce Filgotinib Meets Primary Endpoint in the Phase 3 FINCH 3 Study in Methotrexate-Naïve Rheumatoid Arthritis Patients

March 28, 2019

**-- Filgotinib 100 mg and 200 mg Plus Methotrexate (MTX) Demonstrated Significantly Higher ACR20/50/70 Responses Than Methotrexate Alone --**

**-- Filgotinib Safety Profile Consistent With Previously Reported Results --**

FOSTER CITY, Calif. and 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 3, an ongoing, randomized, double-blind, active-controlled Phase 3 study of filgotinib, an investigational, oral, selective JAK1 inhibitor, in adults with moderately-to-severely active rheumatoid arthritis. FINCH 3 evaluated filgotinib in combination with methotrexate and as monotherapy in MTX-naïve patients. The study achieved its primary endpoint in the proportion of patients achieving an American College of Rheumatology 20 percent response (ACR20) at Week 24. The proportion of patients achieving the primary endpoint of ACR20 response at Week 24 was significantly higher for filgotinib 200 mg plus MTX and filgotinib 100 mg plus MTX compared with MTX alone.

The proportion of patients achieving ACR50, ACR70, and clinical remission (DAS28(CRP) < 2.6) at Week 24 was also significantly higher for patients receiving once-daily filgotinib 100 mg or 200 mg plus MTX compared with patients receiving MTX alone. Additionally, those who received filgotinib experienced greater reduction in the Health Assessment Questionnaire Disability Index (HAQ-DI) compared with those receiving MTX alone at Week 24. Filgotinib 200 mg monotherapy inhibited the progression of structural damage at Week 24 compared with MTX alone as assessed by modified total Sharp score (mTSS).

Top-line FINCH 3 efficacy<sup>†</sup> data are summarized in the table below:

	Filgotinib 200 mg + MTX (n=416) <sup>&amp;</sup>	Filgotinib 100 mg + MTX (n=207) <sup>&amp;</sup>	Filgotinib 200 mg monotherapy (n=210) <sup>&amp;</sup>	MTX (n=416) <sup>&amp;</sup>
ACR20 (%)	81.0 <sup>***</sup>	80.2 <sup>*</sup>	78.1	71.4
ACR50 (%)	61.5 <sup>***</sup>	57.0 <sup>**</sup>	58.1 <sup>**#</sup>	45.7
ACR70 (%)	43.8 <sup>***</sup>	40.1 <sup>***</sup>	40.0 <sup>***#</sup>	26.0
DAS28(CRP) < 2.6 (Clinical remission) (%)	54.1 <sup>***</sup>	42.5 <sup>***</sup>	42.4 <sup>***#</sup>	29.1
HAQ-DI change	-0.94 <sup>***</sup>	-0.90 <sup>**</sup>	-0.89 <sup>*#</sup>	-0.79
mTSS change	0.20	0.22	-0.04 <sup>***#</sup>	0.52

<sup>†</sup>Efficacy assessed at Week 24 for all endpoints

<sup>&</sup>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.

<sup>\*\*\*</sup> p < 0.001, compared with MTX

<sup>\*</sup> p < 0.05, compared with MTX

<sup>\*\*</sup> p < 0.01, compared with MTX

<sup>#</sup> Comparison not adjusted for multiplicity

The safety profile of filgotinib in FINCH 3 is consistent with prior studies up to Week 24. Serious adverse events occurred in 4.1 percent, 2.4 percent, 4.8 percent, and 2.9 percent of patients receiving filgotinib 200 mg plus MTX, filgotinib 100 mg plus MTX, filgotinib 200 mg monotherapy and MTX alone, respectively. There was one venous thrombotic event (in the MTX group), five cases of adjudicated major adverse cardiovascular events (two in the filgotinib 200 mg plus MTX group, one in the filgotinib 200 mg group and two in the MTX group) and one malignancy (in the MTX group). There was one death, reported in the filgotinib 200 mg plus MTX group. Serious infections occurred in 1.0 percent, 1.0 percent, 1.4 percent and 1.0 percent of the patients in the filgotinib 200 mg plus MTX, filgotinib 100 mg plus MTX, filgotinib 200 mg monotherapy and MTX groups, respectively. The proportion of patients reporting herpes zoster was 0.5 percent in each of the treatment groups.

"The FINCH 3 data clearly demonstrate improved efficacy when filgotinib is compared with the use of MTX alone in rheumatoid arthritis patients with earlier stages of disease," said John McHutchison, AO, MD, Chief Scientific Officer, Head of Research and Development, Gilead Sciences. "These data add to the body of evidence from our broader FINCH clinical study program, reinforcing the potential for filgotinib to address important therapeutic needs in people with rheumatoid arthritis."

"Additional effective and tolerable treatment options are still needed for people newly diagnosed with rheumatoid arthritis or in the early stages of the disease. This complements the FINCH 1 and FINCH 2 data, underlining the potential of filgotinib as a treatment option across a wide range of patient populations suffering from rheumatoid arthritis," said Dr. Walid Abi-Saab, Chief Medical Officer, Galapagos.

Detailed findings from FINCH 3 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 3

FINCH 3 is an ongoing 52-week randomized, double-blind and active-controlled study examining filgotinib alone and in combination with MTX, enrolling 1,252 adult patients with moderately to severely active RA who are naïve to MTX. Patients were randomized (2:1:1:2) to receive filgotinib 200 mg plus MTX (n=417), filgotinib 100 mg plus MTX (n=207), filgotinib 200 mg alone (n=210) or MTX (n=418). The primary endpoint is the proportion of patients who achieve an ACR20 response at Week 24.

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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