



# Gilead and Galapagos Announce Filgotinib Meets Primary and All Key Secondary Endpoints in First Phase 3 Study in Rheumatoid Arthritis

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**-- Filgotinib 100 mg and 200 mg Doses Achieved Significantly Higher ACR20/50/70 Responses than Placebo in Patients with Active Rheumatoid Arthritis and Prior Inadequate Response to Biologic Agents --**

**-- Both Filgotinib Doses also Achieved All Key Secondary Efficacy Endpoints, including Low Disease Activity and Clinical Remission --**

**-- Tolerability of Filgotinib was Consistent with Previously Reported Studies --**

FOSTER CITY, Calif. & MECHELEN, Belgium--(BUSINESS WIRE)--Sep. 11, 2018-- Gilead Sciences, Inc. (NASDAQ: GILD) and Galapagos NV (Euronext & NASDAQ: GLPG) today announced that FINCH 2, a global, randomized, placebo-controlled, Phase 3 study of filgotinib, an investigational, selective JAK1 inhibitor, in adults with moderately-to-severely active rheumatoid arthritis and prior inadequate response/intolerance to biologic agents, achieved its primary endpoint in the proportion of patients achieving an American College of Rheumatology 20 percent response (ACR20) at Week 12. Also at Weeks 12 and 24, the proportion of patients achieving ACR50 and ACR70, low disease activity (LDA, DAS28(CRP) ≤ 3.2), and clinical remission (DAS28(CRP) < 2.6) were significantly higher for patients receiving once-daily filgotinib 100 mg or 200 mg compared to patients receiving placebo.

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

	Week 12			Week 24		
	Placebo (n=148) <sup>#</sup>	Filgotinib 100 mg (n=153) <sup>#</sup>	Filgotinib 200 mg (n=147) <sup>#</sup>	Placebo (n=148) <sup>#</sup>	Filgotinib 100 mg (n=153) <sup>#</sup>	Filgotinib 200 mg (n=147) <sup>#</sup>
Non-responder imputation						
ACR20 (%)	31.1	57.5***	66.0***	34.5	54.9***	69.4***
ACR50 (%)	14.9	32.0***	42.9***	18.9	35.3**	45.6***
ACR70 (%)	6.8	14.4*	21.8***	8.1	20.3**	32.0***
DAS28(CRP) ≤ 3.2 (Low disease activity) (%)	15.5	37.3***	40.8***	20.9	37.9**	48.3***
DAS28(CRP) < 2.6 (Clinical remission) (%)	8.1	25.5***	22.4***	12.2	26.1**	30.6***

<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.

\* p <0.05, compared to placebo

\*\* p <0.01, compared to placebo

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

Filgotinib was generally well-tolerated in the FINCH 2 trial, with no new safety signals compared to those reported in previous trials of filgotinib. Treatment-emergent adverse events and serious adverse events were mostly mild or moderate in severity. Serious adverse events occurred in 3.4, 5.2 and 4.1 percent of the patients in the placebo, 100mg and 200mg groups, respectively. The proportion of patients who discontinued study drug due to treatment-emergent adverse events was also similar across groups. Two cases of uncomplicated herpes zoster were reported in each filgotinib group. Two major adverse cardiovascular events (MACE) were identified, one subarachnoid hemorrhage in the placebo group and one myocardial ischemia in the filgotinib 100 mg group. There was one case of non-serious retinal vein occlusion in the filgotinib 200 mg group and no reports of deep venous thrombosis (DVT) or pulmonary embolism (PE). There were no deaths, malignancies, gastrointestinal perforations, or opportunistic infections, including active tuberculosis.

Detailed findings from the FINCH 2 study will be submitted for presentation at a future scientific conference.

"Gilead is committed to the development of new therapies that offer meaningful benefit for people living with rheumatoid arthritis and other serious inflammatory diseases," said John McHutchison, MD, Chief Scientific Officer, Head of Research and Development, Gilead Sciences. "These initial Phase 3 data support the potential of filgotinib, in combination with select disease modifying drugs, to help patients with active rheumatoid arthritis who do not adequately respond to current biologic disease modifying agents. These data are particularly encouraging as we look ahead to Phase 3 results from the ongoing FINCH 1 and 3 trials, which are exploring filgotinib in other populations of patients with rheumatoid arthritis."

"We are pleased that filgotinib has demonstrated significantly improved clinical responses in this difficult to treat population," said Dr. Walid Abi-Saab, Chief Medical Officer at Galapagos. "The good tolerability in this study is also very encouraging."

Filgotinib is investigational and not approved anywhere globally. Its efficacy and safety have not been established. For information about the clinical trials with filgotinib: [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

## About FINCH 2

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 adult patients with moderately-to-severely active rheumatoid arthritis who had not adequately responded to biologic DMARDs (bDMARDs). In this study, 23.7 percent of patients had received three or more bDMARDs. Patients were randomized (1:1:1) to receive filgotinib 100 mg, filgotinib 200 mg or placebo. The primary endpoint was the proportion of patients achieving an ACR20 response at week 12. Protocol-defined non-responders at Week 14 were allowed to complete the trial under standard of care therapy. Treatment-emergent adverse events are those reported during treatment or within 30 days of the last dose of study drug.

For information about clinical trials with filgotinib: [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. Along with FINCH 1 and 3, the Phase 3 FINCH 2 trial is one of several clinical trials of filgotinib in rheumatoid arthritis or other 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) is a clinical-stage biotechnology company specialized in the discovery and development of small molecule medicines with novel modes of action. Galapagos' pipeline comprises Phase 3 through to discovery programs in cystic fibrosis, inflammation, fibrosis, osteoarthritis and other indications. Our target discovery platform has delivered three novel mechanisms showing promising patient results in, respectively, inflammatory diseases, idiopathic pulmonary fibrosis and atopic dermatitis. Galapagos is focused on the development and commercialization of novel medicines that will improve people's lives. The Galapagos group, including fee-for-service subsidiary Fidelia, has approximately 675 employees, operating from its Mechelen, Belgium headquarters and facilities in the Netherlands, France, Switzerland, the US and Croatia. More information at [www.glpg.com](http://www.glpg.com).

### **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 Quarterly Report on Form 10-Q for the quarter ended June 30, 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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