

## **FILGOTINIB DEMONSTRATES DURABLE EFFICACY AND CONSISTENT SAFETY PROFILE AT 52 WEEKS IN FINCH 1 AND 3 STUDIES IN RHEUMATOID ARTHRITIS**

*-- Integrated Safety Analysis from the Phase 3 FINCH and Phase 2 DARWIN Programs Informs Long-Term Safety Profile of Filgotinib in RA --*

*-- Data Presented at The European League Against Rheumatism, EULAR, European E-Congress of Rheumatology 2020 --*

**Foster City, Calif., & Mechelen, Belgium, 4 June, 2020, 07.00 CET** – Gilead Sciences, Inc. (Nasdaq: GILD) and Galapagos NV (Euronext & Nasdaq: GLPG) today announced Week 52 results from the Phase 3 FINCH 1 and FINCH 3 studies of filgotinib, an investigational, oral, selective JAK1 inhibitor, in adults with moderately to severely active rheumatoid arthritis (RA). The data demonstrate sustained efficacy and a consistent safety profile with up to 52 weeks of filgotinib treatment across RA patient populations. The new data are among 15 abstracts on filgotinib in RA that will be presented at the European League Against Rheumatism, EULAR, European E-Congress of Rheumatology 2020.

“Many people with RA struggle with uncontrolled symptoms that affect their daily lives. We are working to develop effective and well-tolerated treatment options that will make a difference in the lives of patients,” said Mark Genovese, MD, Senior Vice President, Inflammation, Gilead Sciences. “These data add to the body of evidence supporting filgotinib as a potential treatment option for a range of RA patients.”

“After more than 4,544 patient years’ exposure thus far, the FINCH and DARWIN programs continue to show that filgotinib has a consistent efficacy and safety profile and has the potential to help more people living with RA achieve symptom control,” said Walid Abi-Saab, MD, Chief Medical Officer at Galapagos.

### *FINCH 1 – 52-Week Data from Phase 3 Study in Patients with Inadequate Response to Methotrexate (Poster #0198)<sup>1</sup>*

The FINCH 1 program evaluated filgotinib versus placebo or adalimumab, on a stable background dose of methotrexate in patients with moderately to severely active RA who had prior inadequate response to methotrexate (MTX-IR). Patients were randomized to receive filgotinib 200 mg once daily (n=475), filgotinib 100 mg once daily (n=480), adalimumab 40 mg bi-weekly (n=325) or matching placebo (n=475). As previously reported, the filgotinib 200 mg group met the primary study endpoint evaluating the proportion of patients who achieved American College of Rheumatology Criteria of at least a 20 percent improvement in the number of tender and swollen joints (ACR20) at Week 12 versus placebo. Filgotinib was superior to placebo in all secondary endpoints pertaining to signs and symptoms of RA, physical function and structural damage.

The majority of patients in FINCH 1 (80.7 percent, n=1,417/1755) completed 52 weeks of treatment with study drug. Both doses of filgotinib showed sustained efficacy in primary and secondary outcome measures at Week 52. In addition, a greater proportion of patients treated with filgotinib 200 mg achieved low disease activity (DAS28(CRP)  $\leq 3.2$ ) and clinical remission (DAS28(CRP)  $< 2.6$ ) compared with adalimumab-treated patients at Week 52 (nominal  $p < 0.05$ ). Rates of remission based on CDAI  $\leq 2.8$  and Boolean remission criteria were also nominally significantly higher in patients receiving filgotinib 200 mg versus adalimumab at Week 52 (nominal  $p < 0.05$ ). Reductions in Health Assessment Questionnaire-Disability

Index from baseline to Week 52 were greater in patients receiving filgotinib 200 mg versus those receiving adalimumab (nominal  $p < 0.05$ ). Response rates were numerically similar between patients treated with filgotinib 100 mg versus adalimumab for these endpoints.

Filgotinib 200 mg and 100 mg demonstrated a consistent safety profile in this study of MTX-IR patients, and no new safety signals were detected through Week 52. There were five deaths reported prior to Week 24; two patients were in the placebo group, two were in the filgotinib 200 mg group and one was in the filgotinib 100 mg group. Four deaths were reported between Weeks 24 and 52; two treated with filgotinib 200 mg, one in the adalimumab group, and one in the placebo group. Adverse events of interest including serious infections, herpes zoster, venous thromboembolism (VTE) and major adverse cardiovascular events (MACE) were infrequent and balanced across treatment groups. Herpes zoster was observed in all treatment groups, with a numeric increase in the filgotinib 200 mg group compared with the filgotinib 100 mg group.

#### *FINCH 3 - Week 52 Data from Phase 3 Study in Methotrexate-Naïve Patients (Poster #0158)<sup>2</sup>*

The FINCH 3 program evaluated filgotinib in patients naïve to methotrexate. Patients were randomized to receive filgotinib 200 mg plus methotrexate ( $n=416$ ), filgotinib 100 mg plus methotrexate ( $n=207$ ), filgotinib 200 mg monotherapy ( $n=210$ ) and methotrexate monotherapy ( $n=416$ ). As previously reported, the filgotinib 200 mg plus methotrexate group met the primary study endpoint evaluating the proportion of patients who achieved ACR20 at Week 24 versus methotrexate monotherapy ( $p < 0.001$ ).

The majority of patients in FINCH 3 (78.1 percent,  $n=975/1,249$ ) received study drug through Week 52. In this analysis, all treatment groups demonstrated sustained efficacy through Week 52 based on clinical response, physical function and radiographic progression. Higher proportions of patients in the filgotinib 200 mg plus methotrexate, 100 mg plus methotrexate and filgotinib 200 mg monotherapy achieved ACR20 (nominal  $p < 0.001$ ,  $p < 0.01$  and  $p < 0.001$ ), ACR50 (nominal  $p < 0.001$ ,  $p < 0.01$  and  $p < 0.01$ ), ACR70 response (nominal  $p < 0.001$ ,  $p < 0.05$ ,  $p < 0.01$ ) and disease remission (nominal  $p < 0.001$  for all three arms) compared with patients receiving methotrexate monotherapy at Week 52. Patients treated with filgotinib 200 mg plus methotrexate (nominal  $p < 0.001$ ) or filgotinib monotherapy (nominal  $p < 0.05$ ) experienced a significantly greater improvement in physical function (measured by reductions in Health Assessment Questionnaire-Disability Index from baseline) compared with those receiving methotrexate alone at Week 52. Patients in the filgotinib treatment groups demonstrated less progression of structural damage at Week 52 with filgotinib 200 mg plus methotrexate (nominal  $p < 0.001$ ); filgotinib 100 mg plus methotrexate and filgotinib 200 mg monotherapy (nominal  $p < 0.05$ ) versus patients receiving methotrexate monotherapy.

Treatment with filgotinib either in combination with methotrexate or as monotherapy demonstrated a consistent safety profile in this study of methotrexate-naïve patients, and no new safety signals were detected. Three deaths were reported in the filgotinib 200 mg plus methotrexate group and one death was reported in the filgotinib 100 mg plus methotrexate group. Adverse events of interest, including rates of infections, serious infections and herpes zoster occurred at similar rates with filgotinib as methotrexate monotherapy. There were no VTEs reported in the filgotinib treatment groups.

In addition to the 52-week FINCH 1 and FINCH 3 study results, new analyses on the safety and efficacy of filgotinib for the treatment of RA will also be presented at the congress.

#### *FINCH 2 - Subgroup Analysis in Patients with Inadequate Response to Biologic DMARDs (Poster #0204)<sup>3</sup>*

Despite currently available treatments, many people living with RA have inadequate responses to biologic disease modifying antirheumatic drugs (bDMARD-IR). In this subgroup analysis of clinical response to filgotinib in bDMARD-IR patients at Week 24, filgotinib demonstrated consistently higher rates of low disease activity and remission versus placebo that were independent of the number of prior bDMARDs or

prior exposure to IL-6 or TNF inhibition. The differences in rates of low disease activity were statistically significant overall for filgotinib 200 mg versus placebo (nominal  $p < 0.001$ ).

Adverse events across subgroups were consistent with the overall study population.

*Integrated Safety Analysis from Phase 3 FINCH and Phase 2 DARWIN Programs (Poster #0202)<sup>4</sup>*

An integrated safety analysis of pooled data from seven clinical trials of filgotinib in the FINCH Phase 3 and DARWIN Phase 2 programs reinforced the consistent safety profile of filgotinib in the treatment of RA, with no new safety concerns identified. Across the trials, 3,827 patients with RA received more than one dose of treatment for a total of 4,544.5 total patient years of exposure.

Exposure-adjusted incidence rates (EAIRs) of serious adverse events or treatment-emergent adverse events leading to death in patients who received filgotinib were comparable with EAIRs in patients treated with placebo, adalimumab or methotrexate; no dose-dependent effects were noted. With filgotinib, EAIR of serious infections and herpes zoster were generally similar to adalimumab and methotrexate. Most cases of herpes zoster were mild to moderate and not serious. The frequency of MACE and VTE were numerically lower for filgotinib relative to placebo. In this integrated analysis, filgotinib was well-tolerated, and no new safety concerns were identified.

Filgotinib is an investigational drug whose efficacy and safety have not been demonstrated. It is not approved for use by any regulatory authority.

**About the Filgotinib Collaboration<sup>5</sup>**

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 rheumatoid arthritis, 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.glp.com](http://www.glp.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 possibility of unfavorable results from ongoing and additional clinical trials involving filgotinib and the

possibility that we are unable to complete one or more of such trials on the currently anticipated timelines. 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 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.

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**Contacts Galapagos****Investors:**

Elizabeth Goodwin  
VP IR  
+1 781 460 1784

Sofie Van Gijssel  
Director IR  
+32 485 19 14 15  
ir@glpg.com

**Media:**

Carmen Vroonen  
Senior Director Communications  
+32 473 824 874

Evelyn Fox  
Director Communications  
+31 6 53 591 999  
communications@glpg.com

**Contacts Gilead****Investors:**

Douglas Maffei, PhD  
+1 650 522 2739

**Media:**

Sonia Choi  
+1 650 425 5483

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<sup>1</sup>Combe, B et al. Efficacy and Safety of Filgotinib for Patients with Rheumatoid Arthritis with Inadequate Response to Methotrexate: FINCH 1 52-Week Results. Abstract at the European League Against Rheumatism, EULAR, European E-Congress of Rheumatology 2020.

<sup>2</sup>Westhovens, R et al. Efficacy and Safety of Filgotinib in Methotrexate-Naïve Patients with Rheumatoid Arthritis: FINCH 3 52-Week Results. Abstract at the European League Against Rheumatism, EULAR, European E-Congress of Rheumatology 2020.

<sup>3</sup>Gottenberg, J-E et al. A Subgroup Analysis of Low Disease Activity and Remission from Phase 3 Study of Filgotinib in Patients with Inadequate Response to Biologic DMARDs. Abstract at the European League Against Rheumatism, EULAR, European E-Congress of Rheumatology 2020.

<sup>4</sup>Genovese, M C et al. Integrated safety Analysis of Filgotinib Treatment for Rheumatoid Arthritis from 7 Clinical Trials. Abstract at the European League Against Rheumatism, EULAR, European E-Congress of Rheumatology 2020.

<sup>5</sup> Gilead & Galapagos Filgotinib Clinical Program Trial Details: FINCH 1 ([NCT02889796](https://clinicaltrials.gov/ct2/show/study/NCT02889796)); FINCH 2 ([NCT02873936](https://clinicaltrials.gov/ct2/show/study/NCT02873936)); FINCH 3 ([NCT02886728](https://clinicaltrials.gov/ct2/show/study/NCT02886728)); SELECTION ([NCT02914522](https://clinicaltrials.gov/ct2/show/study/NCT02914522)); DIVERSITY ([NCT02914561](https://clinicaltrials.gov/ct2/show/study/NCT02914561)); PENGUIN 1 ([NCT04115748](https://clinicaltrials.gov/ct2/show/study/NCT04115748)); PENGUIN 2 ([NCT04115839](https://clinicaltrials.gov/ct2/show/study/NCT04115839))