



## Phase 3 Data on Filgotinib in Biologic-Experienced Rheumatoid Arthritis to Be Presented at 2018 ACR/ARHP Annual Meeting

October 20, 2018

**-- FINCH 2 Study Results Demonstrate Significant Improvement in Rheumatoid Arthritis Signs, Symptoms and Health-Related Quality of Life**

CHICAGO--(BUSINESS WIRE)--Oct. 20, 2018-- Gilead Sciences, Inc. (Nasdaq: GILD) and Galapagos NV (Euronext & NASDAQ: GLPG) today announced detailed results from the Phase 3 FINCH 2 clinical trial of filgotinib, an investigational, selective JAK1 inhibitor, in adults with moderately-to-severely active rheumatoid arthritis and prior inadequate response or intolerance to biologic agents. The data, which are being presented as a late-breaking poster at the 2018 American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting in Chicago, suggest filgotinib has a potential role in addressing important unmet needs in the treatment of rheumatoid arthritis.

Positive efficacy data from FINCH 2 were previously announced in September 2018. The data show statistically significant improvements in the proportion of patients achieving a range of clinical efficacy endpoints, including the proportion of patients achieving American College of Rheumatology 20 percent (ACR20, primary endpoint), 50 percent (ACR50) and 70 percent (ACR70) responses, low disease activity (defined as DAS28(CRP)  $\leq$  3.2) and clinical remission (defined as DAS28(CRP)  $<$  2.6) at Weeks 12 and 24.

Additional FINCH 2 data to be presented include positive results across several patient-reported health-related quality of life measures. Patients receiving filgotinib 100mg or 200mg once-daily experienced greater reduction in the Health Assessment Questionnaire Disability Index (HAQ-DI) at Week 12 compared with those receiving placebo (-0.46 and -0.50 vs -0.19; both  $p < 0.001$ ). Patients receiving filgotinib 100mg or 200mg also experienced greater improvements on the Short-Form Health Survey (SF-36) Physical Component Score (PCS) at Week 12 (7.6 and 8.4 vs 4.2; both  $p < 0.001$ ) and on the Functional Assessment of Chronic Illness Therapy-Fatigue Scale (FACIT-Fatigue) at Week 12 (8.4 and 10.2 vs 5.2;  $p = 0.007$  and  $p < 0.001$ ) compared with patients receiving placebo.

Filgotinib demonstrated a safety profile consistent with earlier clinical trials. Rates of serious treatment-emergent adverse events were similar for the filgotinib 100mg, 200mg and placebo groups (5.2 percent, 4.1 percent and 3.4 percent, respectively). The proportion of patients who discontinued study drug due to treatment-emergent adverse events was also similar across groups. Serious infections occurred at similar rates across the three study arms (2.0 percent, 0.7 percent and 1.4 percent, respectively). A total of four cases of uncomplicated Herpes zoster occurred in the filgotinib arms, and one non-serious case of retinal vein occlusion was reported in the filgotinib 200 mg group. Two major adverse cardiovascular events were reported, one in the filgotinib 100mg group and one in the placebo group. No deaths occurred during the study.

"Inflammatory diseases are an important area of focus for Gilead's research and development and filgotinib is a cornerstone of this work," said John McHutchison, AO, MD, Chief Scientific Officer and Head of Research and Development, Gilead Sciences. "The results of FINCH 2 add further support to the potential role of filgotinib in treating patients with rheumatoid arthritis."

"For many people living with rheumatoid arthritis, the effects of pain, inflammation and fatigue can take a serious toll in their everyday lives. We are encouraged by these data, which suggest filgotinib can improve symptoms of rheumatoid arthritis in patients who have not responded to prior biologic treatment and who need new therapies that are safe and effective," said Dr. Walid Abi-Saab, Chief Medical Officer at Galapagos. "We are committed to developing filgotinib to address the unmet needs of these patients."

Filgotinib is an investigational compound and is 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 the FINCH 2 Trial

FINCH 2 was a global, 24-week, randomized, double-blind, placebo-controlled, Phase 3 study evaluating daily oral filgotinib on a background of conventional synthetic disease-modifying anti-rheumatic drug(s) (csDMARDs) in adult patients with moderately-to-severely active rheumatoid arthritis who had not adequately responded (or were intolerant) to prior biologic DMARDs (bDMARDs). In this study, 23.4 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. Treatment-emergent adverse events are those reported during the study 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. Ongoing clinical studies include the FINCH Phase 3 program in rheumatoid arthritis, the DIVERSITY Phase 3 trial in Crohn's disease, the Phase 2b/3 SELECTION trial in ulcerative colitis and Phase 2 studies in small bowel and fistulizing Crohn's disease, psoriatic arthritis, ankylosing spondylitis, Sjogren's syndrome, lupus and uveitis.

### 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 inflammation, fibrosis, cystic 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. Our ambition is to become a leading global biopharmaceutical company, focused on the development and commercialization of innovative medicines that will improve people's lives. The Galapagos group, including fee-for-service subsidiary Fidelta, 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.gilead.com](http://www.gilead.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 Statement

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 filgotinib. 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 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 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.

View source version on businesswire.com: <https://www.businesswire.com/news/home/20181020005019/en/>

Source: Gilead Sciences, Inc.

## Galapagos Contacts

### Investors:

Elizabeth Goodwin, +1-781-460-1784

VP IR & Corporate Communications

[ir@gilpg.com](mailto:ir@gilpg.com)

Sofie Van Gijssel, +32 485 191415

Director IR

[ir@gilpg.com](mailto:ir@gilpg.com)

or

### Media:

Evelyn Fox, +31 6 53 591 999

Director Communications

[communications@gilpg.com](mailto:communications@gilpg.com)

or

## Gilead Contacts

### Investors:

Sung Lee, +1 650-524-7792

or

### Media:

Nathan Kaiser, +1 650-522-1853