



## **GILEAD AND GALAPAGOS ANNOUNCE EFFICACY AND SAFETY RESULTS OF FILGOTINIB THROUGH 52 WEEKS IN FINCH 1 AND FINCH 3 STUDIES IN RHEUMATOID ARTHRITIS**

**Foster City, Calif. and Mechelen, Belgium; October 11, 2019, 0.00 CET;** – Gilead Sciences, Inc. (NASDAQ: GILD) and Galapagos NV (Euronext & NASDAQ: GLPG) today announced that Week 52 data from the registrational Phase 3 FINCH 1 and FINCH 3 trials of filgotinib, an investigational, oral, selective JAK1 inhibitor, for the treatment of moderately-to-severely active rheumatoid arthritis (RA) are consistent with and support the efficacy, safety and tolerability profiles demonstrated in the Week 12 and 24 analyses presented earlier this year.

“We are encouraged by the durability of both the efficacy and safety profiles of filgotinib seen in these studies,” said John Sundy, MD, PhD, Senior Vice President, Inflammation and Respiratory Diseases, Gilead Sciences. “These data suggest that filgotinib if approved, may play an important role in helping people living with rheumatoid arthritis achieve sustained, clinically meaningful responses.”

“These recent updates from the FINCH 1 and 3 trials continue to provide consistent evidence to support filgotinib’s profile in RA patients. In the second half of the FINCH 1 and FINCH 3 trials, filgotinib exhibited the same favorable safety profile seen in the first 24 weeks, including similar rates of thrombotic events as previously observed, as well as persistent efficacy,” said Dr. Walid Abi-Saab, Chief Medical Officer, Galapagos.

Detailed Week 52 results from the FINCH 1 and 3 trials will be submitted for presentation at a future medical conference.

A Marketing Authorization Application (MAA) for filgotinib for the treatment of adults with rheumatoid arthritis is now under evaluation by the European Medicines Agency (EMA), and a New Drug Application (NDA) for filgotinib has been submitted to the Japanese Ministry of Health, Labor and Welfare (MHLW). Gilead plans to file a New Drug Application (NDA) for filgotinib for the treatment of rheumatoid arthritis in the United States including the FINCH 1 and FINCH 3 Week 52 data later this year.

Filgotinib is an investigational agent and is not approved anywhere. Its efficacy and safety have not been established by any regulatory authorities.

### **About the FINCH 1 and FINCH 3 programs**

The FINCH Phase 3 program investigated the efficacy and safety of 100 mg and 200 mg filgotinib once daily, in RA patient populations ranging from early stage to biologic-experienced patients. **FINCH 1** was a 52-week, randomized, placebo- and adalimumab-controlled trial in combination with methotrexate (MTX) enrolling 1,759 adult patients with moderately to severely active RA who had inadequate response to MTX. The primary endpoint was ACR20 at week 12. The trial included radiographic assessment at weeks 24 and 52. **FINCH 3** was a 52-week, randomized trial in 1,252 MTX-naïve patients to evaluate filgotinib 200mg alone and filgotinib 100 mg or 200 mg combined with methotrexate versus methotrexate

alone in methotrexate-naïve patients. The primary endpoint was ACR20 at week 24. Radiographic progression was also assessed.

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

### **About the Filgotinib Collaboration**

Galapagos and Gilead entered into a global collaboration for the development and commercialization of filgotinib in inflammatory indications. The FINCH Phase 3 studies are among several clinical trials of filgotinib in inflammatory diseases, including the EQUATOR Phase 2 program in psoriatic arthritis, the TORTUGA Phase 2 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.glp.com](http://www.glp.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 that the final efficacy, safety and tolerability results from these studies differ materially from those reported in this press release, the possibility of unfavorable results from other clinical trials involving filgotinib, and the risk that the EMA, FDA and other regulatory agencies may not approve filgotinib for the treatment of RA in the currently anticipated timelines or at all, and any marketing approvals, if granted, may have significant limitations on its use. 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, 2019, 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 Contacts**

#### **Investors:**

Elizabeth Goodwin  
VP IR  
+1-781-460-1784

Sofie Van Gijsel  
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

### **Gilead Contacts**

#### **Investors:**

Sung Lee  
+1 650-524-7792

#### **Media:**

Arran Attridge  
+1 650-425-8975