



# GILEAD AND GALAPAGOS ANNOUNCE RESULTS WITH FILGOTINIB IN THE PHASE 2 EQUATOR STUDY IN PSORIATIC ARTHRITIS AND PROGRESSION INTO PHASE 3 FOR THE SELECTION STUDY IN ULCERATIVE COLITIS

# -- EQUATOR Achieves Primary Endpoint of ACR20 Response at Week 16 --

# -- Galapagos to Receive \$15 Million Payment from Gilead for Progression into Phase 3 of the Phase 2b/3 SELECTION Study of Filgotinib in Ulcerative Colitis --

Foster City, Calif. and Mechelen, Belgium; May 30 2018, 22.01 CET; Regulated information – Gilead Sciences, Inc. (NASDAQ: GILD) and Galapagos NV (Euronext & NASDAQ: GLPG) announced that the randomized, placebo-controlled Phase 2 EQUATOR study of filgotinib, an investigational, selective JAK1 inhibitor, in 131 adults with moderate to severe psoriatic arthritis, achieved its primary endpoint of improvement in the signs and symptoms of psoriatic arthritis at Week 16, as assessed by the American College of Rheumatology 20 percent improvement score (ACR20). There was an ACR20 response of 80 percent for filgotinib versus 33 percent for placebo (p<0.001). The ACR50 and ACR70 responses at Week 16 were also significantly higher for filgotinib versus placebo (ACR50: 48 percent for filgotinib versus 15 percent, p<0.001; ACR70: 23 percent versus 6 percent, p<0.01).

Filgotinib was generally well-tolerated in the EQUATOR trial, with no new safety signals observed and similar laboratory changes compared to those reported in previous trials with filgotinib in rheumatoid arthritis patients. The adverse event rate was similar in both groups with mostly mild or moderate events reported. There was one serious infection in the filgotinib group, a patient who experienced pneumonia with a fatal outcome. One other patient receiving filgotinib developed herpes zoster. There were no cases of opportunistic infection, tuberculosis, thromboembolism, or malignancy.

"The data from the EQUATOR study are very impressive and indicate that filgotinib has the potential to have a significant effect on signs and symptoms of psoriatic arthritis, a condition where there is still a high unmet medical need," said Dr. Philip Mease, Director of Rheumatology Research, Swedish-Providence-St. Joseph Health Systems and Clinical Professor, University of Washington, Seattle, WA.

"We are pleased to report that filgotinib remains consistent in terms of activity and tolerability, now also in psoriatic arthritis," said Dr. Walid Abi-Saab, Chief Medical Officer at Galapagos.

Detailed results from the EQUATOR trial will be submitted for presentation at a future scientific conference.

Separately, Gilead and Galapagos also announced that an independent Data Monitoring Committee (DMC) conducted a planned interim futility analysis of the filgotinib Phase 2b/3 ulcerative colitis study, SELECTION, after 350 patients completed the induction period in the Phase 2b portion of the study. The DMC recommended that the study proceed into Phase 3 as planned at both the 100 mg and 200 mg once daily dose level in biologic-experienced and biologic-naïve patients.

Galapagos is to receive a \$15 million payment from Gilead for this progression from Phase 2 to Phase 3 in the SELECTION trial.

"We continue to see great potential with filgotinib to treat a range of inflammatory diseases," said John McHutchison, MD, Chief Scientific Officer, Head of Research and Development, Gilead. "As such, we are pleased with the continued progress of the development programs, including the EQUATOR results and advancing the SELECTION study into Phase 3."





Filgotinib is investigational and its efficacy and safety have not been established. For information about the clinical trials with filgotinib: www.clinicaltrials.gov.

### About the EQUATOR Trial

Initiated by Galapagos in April 2017, the EQUATOR Phase 2 trial was a multi-center, randomized, double-blind, placebo-controlled trial to assess the safety and efficacy of the selective JAK1 inhibitor filgotinib in adult patients with moderately to severely active psoriatic arthritis. EQUATOR was conducted in Ukraine, Poland, Estonia, Bulgaria, Spain, Czech Republic, and Belgium. In total 131 patients were randomized in a 1:1 ratio to receive filgotinib 200 mg or placebo once-daily administered for 16 weeks; 85 percent of the patients were naïve to TNF treatment.

The primary objective of EQUATOR was to evaluate the effect of filgotinib compared to placebo on the signs and symptoms of psoriatic arthritis, as assessed by ACR20 at Week 16. Secondary objectives included ACR50/70 and minimum disease activity (MDA) as well as the effects of filgotinib on psoriasis, dactylitis (whole finger inflammation) and enthesitis (inflammation of the tendons).

# About Psoriatic Arthritis

Psoriatic arthritis is an inflammatory form of arthritis, affecting up to 30 percent of psoriasis patients. Psoriatic arthritis can cause swelling, stiffness and pain in and around the joints, cause nail changes and overall fatigue. Studies show that delaying treatment for psoriatic arthritis as little as six months can result in permanent joint damage. Early recognition, diagnosis and treatment of psoriatic arthritis are critical to relieve pain and inflammation and help prevent joint damage. Despite the availability of a number of treatment options, few current treatments effectively relieve enthesitis and symptoms in the joints and the skin.

### About the SELECTION Phase 3 Trial

Initiated by Gilead in late 2016, the SELECTION Phase 2b/3 trial is a multi-center, randomized, doubleblind, placebo-controlled study to assess the safety and efficacy of the selective JAK1 inhibitor filgotinib in adult patients with moderately to severely active ulcerative colitis. A total of 1,300 patients are targeted to be randomized to receive filgotinib 100 mg, 200 mg, or placebo once-daily administered for 58 weeks. The primary objective of SELECTION is to evaluate the efficacy of filgotinib as compared to placebo in establishing EBS (endoscopy, bleeding, stool) remission at Week 10.

### About the Galapagos – Gilead Collaboration

Galapagos and Gilead entered into a global collaboration for the development and commercialization of filgotinib in inflammatory indications. The Phase 2 EQUATOR trial in psoriatic arthritis is one of several Phase 2 trials in inflammatory diseases that were initiated in 2017 in addition to the ongoing FINCH Phase 3 program in rheumatoid arthritis, the DIVERSITY Phase 3 trial in Crohn's disease (also small bowel and fistulizing Crohn's disease Phase 2 studies) and the Phase 2b/3 SELECTION trial in ulcerative colitis.

# 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 <u>www.gilead.com</u>.

### 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 Fidelta, has approximately 640 employees, operating from its Mechelen, Belgium headquarters and facilities in the Netherlands, France, Switzerland, the US and Croatia. More information at <u>www.glpg.com</u>.

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).

### **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 forwardlooking 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 statements**

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 parties' ability to complete the clinical trial programs evaluating filgotinib for the treatment of psoriatic arthritis, ulcerative colitis and other inflammatory diseases in the currently anticipated timelines, or at all. In addition, there is the possibility of unfavorable results from 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 March 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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