



Positive Trial Results with Filgotinib in Psoriatic Arthritis and Ankylosing Spondylitis Both Published in The Lancet

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-- Phase 2 EQUATOR Data Demonstrating Efficacy in Psoriatic Arthritis Also Presented in a Plenary Session at 2018 ACR/ARHP Annual Meeting --

CHICAGO--(BUSINESS WIRE)--Oct. 22, 2018-- Gilead Sciences, Inc. (Nasdaq: GILD) and Galapagos NV (Euronext & NASDAQ: GLPG) today announced that detailed results from two clinical trials evaluating filgotinib, an investigational, selective JAK1 inhibitor, for the treatment of psoriatic arthritis and ankylosing spondylitis were both published in *The Lancet*. The publication of the Phase 2 EQUATOR data also coincides with a plenary session presentation at the 2018 American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting.

"The results of the EQUATOR and TORTUGA studies demonstrate that filgotinib improved the signs and symptoms of patients with psoriatic arthritis whose disease had not responded to prior therapies and independently, for those with ankylosing spondylitis," said John McHutchison, AO, MD, Chief Scientific Officer and Head of Research and Development, Gilead Sciences. "These findings represent an important step forward in our efforts to improve outcomes for people living with these inflammatory diseases."

"We are pleased that filgotinib demonstrates a consistent safety and efficacy profile across multiple inflammatory conditions, including psoriatic arthritis and ankylosing spondylitis," said Dr. Walid Abi-Saab, Chief Medical Officer at Galapagos. "We look forward to sharing additional updates as we continue to develop this compound for patients in need of additional therapy options."

Phase 2 EQUATOR Study in Psoriatic Arthritis [ACR/ARHP Abstract #1821]

Data from EQUATOR, a placebo-controlled trial of 131 adults with moderately to severely active psoriatic arthritis who had an inadequate response or were intolerant to at least one conventional disease-modifying anti-rheumatic drug (cDMARD), demonstrated the efficacy of filgotinib in this patient population. The study achieved its primary endpoint at Week 16, with 80 percent of patients on filgotinib 200mg once-daily achieving ACR20, compared with 33 percent on placebo ($p < 0.001$). ACR50 and ACR70 responses at Week 16 were also significantly higher for filgotinib compared with placebo (ACR50: 48 percent for filgotinib vs 15 percent for placebo, $p < 0.001$; ACR70: 23 percent vs 6 percent, $p < 0.01$). These data were previously announced in May 2018.

The study also found greater improvement in disease signs and symptoms for patients receiving filgotinib 200mg once-daily compared with placebo at Week 16, as measured by Minimal Disease Activity (MDA) (23 percent vs 9 percent, $p < 0.05$) and the Psoriasis Area and Severity Index 75 percent improvement from baseline (PASI75) (45 percent vs 15 percent, $p < 0.01$). The data showed greater improvement from baseline in the Health Assessment Questionnaire Disability Index (HAQ-DI) for those receiving filgotinib compared with placebo (-0.57 vs -0.28, $p < 0.001$).

Safety-related outcomes were similar between the filgotinib and placebo arms of the study, including rates of treatment-emergent adverse events (57 percent and 59 percent, respectively) and infections and infestations (22 percent and 21 percent). Two serious treatment-emergent adverse events were reported: one hip fracture in the placebo group and one case of fatal pneumonia in the filgotinib treatment group, which was the only serious infection and the only death in the study. No deep venous thrombosis, pulmonary embolism, malignancies, gastrointestinal perforations, opportunistic infections/active tuberculosis or cases of Herpes zoster were reported.

"Effective treatment for psoriatic arthritis is critical for relieving pain and inflammation and helping to prevent joint damage. Unfortunately, not all patients respond to currently available therapies," said Philip J. Mease, MD, Director of Rheumatology Research, Swedish-Providence-St. Joseph Health Systems and Clinical Professor, University of Washington. "These results indicate that filgotinib has the potential to address the needs of individuals who require additional treatment options."

Phase 2 TORTUGA Study in Ankylosing Spondylitis

In the Phase 2 TORTUGA study, adults with moderately to severely active ankylosing spondylitis who were treated with filgotinib 200mg once-daily achieved significantly greater improvements in AS Disease Activity Score (ASDAS), the primary endpoint, at Week 12. The mean change from baseline in ASDAS was -1.5 for patients treated with filgotinib versus -0.6 for those treated with placebo ($p < 0.0001$). ASAS20 and ASAS40 responses at Week 12 were also significantly higher for filgotinib compared with placebo (ASAS20: 76 percent for filgotinib vs 40 percent for placebo, $p < 0.0001$; ASAS40: 38 percent vs 19 percent, $p < 0.05$).

Adverse events were generally mild or moderate in severity and were reported in an equal proportion of patients in the filgotinib and placebo groups (31 percent). Laboratory changes were consistent with those previously reported for filgotinib, and no new safety signals were observed in the study. There was one treatment-emergent serious adverse event of pneumonia reported for a patient receiving filgotinib who recovered after hospital-based antibiotic treatment. One patient with an inherited risk for thrombosis who was randomized to filgotinib experienced a non-serious deep venous thrombosis after completing the course of study drug. No deaths, malignancies, hepatic events, gastrointestinal perforations, opportunistic infections/active tuberculosis, or cases of Herpes zoster were reported.

Full results of both studies are now available in [The Lancet](#):

Efficacy and safety of filgotinib, a selective Janus kinase 1 inhibitor, in patients with active psoriatic arthritis (EQUATOR): results from a randomised, placebo-controlled, phase 2 trial: [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(18\)32483-8/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)32483-8/fulltext)

Efficacy and safety of filgotinib, a selective Janus kinase 1 inhibitor, in patients with active ankylosing spondylitis (TORTUGA): results from a randomised, placebo-controlled, phase 2 trial: [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(18\)32463-2/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)32463-2/fulltext)

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.

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 filgotinib in adult patients with moderately to severely active psoriatic arthritis who had an inadequate response or were intolerant to conventional disease-modifying anti-rheumatic drugs (cDMARDs). 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 once-daily oral filgotinib 200mg or placebo for 16 weeks; 85 percent of the patients were naïve to anti-TNF treatments.

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 the proportion of patients achieving ACR20 at Week 16. Secondary objectives included the proportion of patients achieving ACR50/70 and MDA as well as the effects of filgotinib on psoriasis, dactylitis (whole finger inflammation) and enthesitis (inflammation of the tendons).

About the TORTUGA Study

TORTUGA was a multi-center, randomized, double-blind, placebo-controlled, Phase 2 study to assess the safety and efficacy of filgotinib in adult patients with moderately to severely active AS. The trial was conducted in Belgium, Bulgaria, Czech Republic, Estonia, Poland, Spain and Ukraine. In total, 116 patients were randomized in a 1:1 ratio to receive filgotinib 200 mg or placebo once daily for 12 weeks.

The primary objective of TORTUGA was to evaluate the effect of filgotinib compared to placebo on the signs and symptoms of AS, as assessed at Week 12 by ASDAS (a standard composite index for assessing the disease, which incorporates five disease activity variables).

About the Galapagos – Gilead Collaboration

Galapagos and Gilead entered into a global collaboration for the development and commercialization of filgotinib in inflammatory indications. Filgotinib is being investigated in several clinical trials in inflammatory diseases, including the Phase 3 trials in rheumatoid arthritis FINCH 1, 2 and 3, 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 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. 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 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.

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.

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 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 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.

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Galapagos Contacts

Investors:

Elizabeth Goodwin, +1-781-460-1784

VP IR & Corporate Communications

ir@glpg.com

Sofie Van Gijssel, +32 485 191415

Director IR

ir@glpg.com

or

Media:

Evelyn Fox, +31 6 53 591 999

Director Communications

communications@glpg.com

or

Gilead Contacts

Investors:

Sung Lee, +1 650-524-7792

or

Media:

Nathan Kaiser, +1 650-522-1853