



NEW ANALYSES OF PHASE 2 EQUATOR CLINICAL PROGRAM SUPPORT DURABLE EFFICACY OF FILGOTINIB IN PSORIATIC ARTHRITIS

-- Data Were Presented at the European League Against Rheumatism, EULAR, European E-Congress of Rheumatology 2020 --

Foster City, Calif., & Mechelen, Belgium, 5 June 2020, 22.01 CET – Gilead Sciences, Inc. (Nasdaq: GILD) and Galapagos NV (Euronext & Nasdaq: GLPG) today announced new analyses from two clinical trials evaluating filgotinib, an investigational, oral, selective JAK1 inhibitor, in adults with psoriatic arthritis (PsA). The data from the double-blind, placebo-controlled, Phase 2 EQUATOR study and the EQUATOR-2 open-label extension study demonstrate filgotinib’s durable efficacy and consistent safety profile in people with active PsA, and showed rapid and sustained reductions in inflammatory biomarkers in patients with moderate to severe PsA. The new analyses were presented at the European League Against Rheumatism, EULAR, European E-Congress of Rheumatology 2020.

“Despite existing treatments, people living with psoriatic arthritis can face challenging long-term symptoms including joint swelling and stiffness, pain and fatigue – all of which can significantly impact patients’ daily lives,” said Mark Genovese, MD, Senior Vice President, Inflammation, Gilead Sciences. “These new analyses from the EQUATOR study program showed that patients with PsA treated with filgotinib achieved a sustained response. We look forward to advancing the pivotal Phase 3 PENGUIN clinical trial program to confirm the safety and efficacy of filgotinib as a potential treatment option for this patient population.”

“The data from the Phase 2 program for filgotinib in psoriatic arthritis add to the growing body of evidence for the efficacy and safety profile of this investigational treatment,” said Walid Abi-Saab, MD, Chief Medical Officer, Galapagos. “We are particularly encouraged by the innovative analysis of the impact of filgotinib at the molecular level, which indicates the drug is acting rapidly to reduce the hallmarks of inflammation in this condition.”

Efficacy and safety of filgotinib in patients with active PsA: Subgroup analyses from a randomized, placebo-controlled, Phase 2 trial (EQUATOR) (Poster #0343)¹

In a new subgroup analysis of patients with active PsA in the 16-week EQUATOR Phase 2 trial, the effects of filgotinib on key efficacy endpoints were generally consistent across a range of patient subgroups, including sex, body mass index, disease duration, baseline disease severity, concurrent use of disease-modifying antirheumatic drugs and prior exposure to tumor necrosis factor inhibitors.

Filgotinib consistently demonstrated a statistically significant higher proportion of patients achieving ACR20 response compared with placebo across all subgroups. Similarly, filgotinib achieved a higher proportion of ACR50 response and Psoriatic Arthritis Disease Activity Score (PASDAS) of low disease activity, compared with placebo, reaching statistical significance in most subgroups. Treatment differences for Disease Activity Index for Psoriatic Arthritis (DAPSA) consistently favored filgotinib, reaching statistical significance in most subgroups as well. There were no clinically relevant differences when comparing response to filgotinib across subgroups.

Filgotinib demonstrated a consistent safety profile and no new safety signals were identified in this study.

Long-term efficacy of filgotinib in PsA: Week 52 response patterns from an open-label extension (OLE) study (EQUATOR-2) (Poster #0339)²

Nearly all (98.4 percent, 122/124) of the patients who completed the 16-week EQUATOR trial enrolled in the EQUATOR-2 OLE study. The median exposure to filgotinib in both EQUATOR and the OLE study was 66 weeks. An interim analysis at Week 52 demonstrated sustained efficacy with filgotinib across several measures of disease activity and treatment response in patients with active PsA.

The majority of patients who achieved minimal disease activity (MDA) and ACR50 response in the original EQUATOR trial maintained MDA and ACR50 at Week 52 and a proportion of non-responders in EQUATOR achieved these responses in the OLE study. In total, at Week 52 of the OLE study, 33.6 percent of patients achieved MDA response and 55.0 percent achieved ACR50 response in this observed case analysis. No new safety signals were observed.

*Effect of filgotinib on inflammatory biomarkers in patients with moderate to severe PsA (Oral #0224)*³

Finally, in a new biomarker analysis of samples from the EQUATOR trial, treatment with filgotinib demonstrated significantly greater reductions from baseline in levels of circulating biomarkers associated with PsA disease activity, compared with placebo. Filgotinib treatment reduced cytokines involved in both systemic inflammation, such as IL-6 and SAA, as well as psoriasis-associated pathology, such as IL-17AF and IL-12, reflecting the improvements in clinical scores observed in EQUATOR. These findings are consistent with reduced disease activity in patients with PsA and suggest that filgotinib treatment leads to a sustained reduction of inflammation in PsA.

Filgotinib is an investigational agent and is not approved by the FDA or any other regulatory authority. For information about the clinical trials with filgotinib, visit www.clinicaltrials.gov.

About the Filgotinib Collaboration⁴

Gilead and Galapagos 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.

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.

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.

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 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.

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¹ Helliwell PS, et al. Efficacy and safety of filgotinib, a selective Janus kinase 1 inhibitor, in patients with active psoriatic arthritis: Subgroup analyses from a randomized, placebo-controlled, Phase 2 trial (EQUATOR) Abstract at the European League Against Rheumatism (EULAR), E-Congress of Rheumatology 2020.

² Gladman DD, et al. Long-term efficacy of the oral selective Janus kinase 1 inhibitor filgotinib in psoriatic arthritis: Week 52 response patterns in individual patients from an open-label extension (OLE) study (EQUATOR2). Abstract at the European League Against Rheumatism (EULAR), E-Congress of Rheumatology 2020.

³ Gladman D, et al. Filgotinib treatment leads to rapid and sustained reductions in inflammatory biomarkers in patients with moderate to severe psoriatic arthritis. Abstract at the European League Against Rheumatism (EULAR), E-Congress of Rheumatology 2020.

⁴ Gilead & Galapagos Filgotinib Clinical Program Trial Details: FINCH 1 ([NCT02889796](#)); FINCH 2 ([NCT02873936](#)); FINCH 3 ([NCT02886728](#)); SELECTION ([NCT02914522](#)); DIVERSITY ([NCT02914561](#)); PENGUIN 1 ([NCT04115748](#)); PENGUIN 2 ([NCT04115839](#))