New Data on Filgotinib in Rheumatoid Arthritis (RA) Demonstrate Durable Efficacy and Safety Profile

November 9, 2019

-- Pooled Analysis from the FINCH RA Clinical Program with Investigational Filgotinib Reinforces Favorable Safety and Tolerability Profile Alone and in Combination with Methotrexate (MTX) or Conventional Disease-Modifying Antirheumatic Drug(s) (csDMARDs) --

-- Data Demonstrate Efficacy and Safety Across a Wide Range of Patient Populations, Including Those Intolerant or Unresponsive to Biologic Treatment --

-- Data to be Presented at 2019 ACR/ARP Annual Meeting --

FOSTER CITY, Calif. & MECHELEN, Belgium--(BUSINESS WIRE)--Nov. 9, 2019-- Gilead Sciences, Inc. (Nasdaq: GILD) and Galapagos NV (Euronext & NASDAQ: GLPG) today announced detailed results from the companies' clinical research program evaluating filgotinib, an investigational, oral, selective JAK1 inhibitor, in adults with moderately-to-severely active RA. The data demonstrate durable efficacy and safety results with filgotinib across multiple RA patient populations, from MTX-naïve patients to those who have had an inadequate response to two or more biologic disease-modifying antirheumatic drugs (bDMARDs). The analyses will be presented at the 2019 American College of Rheumatology/Association of Rheumatology Professionals (ACR/ARP) Annual Meeting in Atlanta.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20191109005041/en/

"These new analyses continue to demonstrate the consistent efficacy and safety profile of filgotinib for a broad range of patients, including those who have already tried other treatments and require other effective and tolerable options," said John Sundy, MD, PhD, Senior Vice President, Inflammation and Respiratory Diseases, Gilead Sciences. "With the presentation of these results at ACR, we are one step closer in our journey to deliver upon the promise of filgotinib for patients in need."

"People living with RA often struggle with debilitating, long-term symptoms that can negatively impact their quality of life," said Dr. Walid Abi-Saab, Chief Medical Officer, Galapagos. "These latest analyses continue to support the clinical potential of filgotinib in RA patients whose disease activity may not be adequately controlled by current treatments."

Efficacy Sustained in Difficult-to-Treat RA Populations

Abstract #517

A subgroup analysis from the Phase 3 FINCH 2 trial evaluating once-daily doses of filgotinib 200 mg and 100 mg with a stable dose of csDMARDs in 449 patients who previously had an inadequate response to biologic DMARD therapy (bDMARD-IR) showed that both doses of filgotinib improved clinical outcomes versus placebo, regardless of the number and mechanism of action (MOA) of prior bDMARDs. After 12-weeks of treatment, 70.3 percent of subjects treated with 200 mg of filgotinib and 58.2 percent of subjects treated with 100 mg of filgotinib achieved an ACR20 score compared with only 25.7 percent of placebo-treated subjects. Additionally, 68 percent of bDMARD-IR patients in the filgotinib 200 mg group and 51.2 percent of bDMARD-IR patients in the 100 mg group who had been treated with more than one biologic MOA achieved ACR20 response versus placebo (27.3 percent).

Abstract #504

A separate analysis of the FINCH 2 trial assessed the efficacy of once-daily filgotinib 200 mg or 100 mg versus placebo for 24 weeks across prespecified subgroup characteristics such as disease duration/activity, seropositivity and concurrent medication use. Filgotinib efficacy was measured by ACR20 and Disease Activity Scores 28 (DAS). Results demonstrate that, compared with placebo, filgotinib consistently improved clinical outcomes in bDMARD-IR patients and that treatment efficacy was not impacted by any of these demographic and clinical baseline characteristics.

Latest Analyses Demonstrate Consistent Safety Profile

Abstract #1329

The safety and tolerability of filgotinib as a monotherapy and in combination with MTX or csDMARDs were found to be favorable in a pooled safety analysis across the randomized, multicenter Phase 3 FINCH 1, 2 and 3 studies at both the 200 mg and 100 mg doses. The pooled analysis assessed a total of 3,452 patients with moderately to severely active RA who had an inadequate response to MTX (FINCH 1), who were receiving csDMARDs and had an inadequate response to bDMARDs (FINCH 2) or who were MTX-naïve (FINCH 3).

Pooled safety results across groups indicate that the frequency of adjudicated positive major adverse cardiac events (MACE), herpes zoster virus, deep vein thrombosis (DVT) and pulmonary embolism (PE) was similar across groups for patients treated with filgotinib as monotherapy, in combination with MTX or in combination with csDMARDs. The incidences of adjudicated positive MACE were 0.2 percent in both the filgotinib 200 and 100 mg treatment groups, 0.3 percent in the adalimumab-treated groups, and 0.5 percent in the placebo plus MTX or csDMARD-treated group. Additionally, the incidences of DVT/PE were less than 0.1 percent in the 200 mg monotherapy, filgotinib 100 mg and 200 mg plus MTX or csDMARD treatment groups, 0 percent in the adalimumab treatment group and 0.3 percent in the placebo plus MTX or csDMARD treatment group. The same rate of patient deaths (0.2 percent) was reported in the placebo plus MTX/csDMARD treatment group and across the filgotinib 200 mg and 100 mg plus MTX/csDMARD combination groups. The treatment-emergent adverse events (TEAEs) of interest were also similar across groups, and the most common TEAEs were infections.

Abstract #2875

A separate analysis from the FINCH 2 trial assessed shifts from baseline after 12- and 24-weeks of treatment in hemoglobin, platelets, neutrophils and lymphocytes which all remained consistent throughout the study. At baseline, 129 (28.8 percent), 4 (0.9 percent), 10 (2.2 percent) and 26 (5.8 percent)

patients had mild-moderate low levels of hemoglobin, platelets, neutrophils and lymphocytes, respectively, and 5 (1.1 percent) had severely low levels of lymphocytes.

Of the 129 patients with mild-moderate low hemoglobin at baseline, 27 of 82 patients in the filgotinib treatment groups shifted towards hemoglobin normalization at week 12, with similar patterns observed for platelet, lymphocyte and neutrophil counts. These results suggest that filgotinib, which selectively inhibits JAK1, may not increase the incidence of anemia, thrombocytopenia or leukopenia.

Long-Term Safety and Efficacy of Filgotinib

Abstract #550

Data comprising 2,203 patient-years of exposure (PYE) with filgotinib from the Phase 2b, open-label extension DARWIN 3 study assessed the long-term safety and efficacy of filgotinib (200 mg or 100 mg) monotherapy and filgotinib plus MTX in 739 patients. An observed-case analysis at week 156 found that 89.7, 63 and 40 percent of patients in the filgotinib monotherapy group achieved ACR20/50/70 responses, respectively. In the filgotinib plus MTX group, 87.2 percent, 72.4 percent and 45.5 percent of patients in the filgotinib plus MTX group achieved ACR20/50/70 responses, respectively. TEAEs occurred in 83.9 percent (n=203) of the filgotinib monotherapy group and in 84.3 percent (n=419) of the filgotinib plus MTX group. Serious TEAEs occurred in 13.6 percent (n=33) of the filgotinib monotherapy group and 9.1 percent (n=45) of the filgotinib plus MTX group. Rates of herpes zoster in the filgotinib monotherapy group and filgotinib plus MTX groups were 1.6 and 1.5 events per 100 PYE, respectively. Additionally, event rates of serious infection across these treatment groups were 0.9 and 2.0 per 100 PYE. These results indicate that filgotinib efficacy was sustained through 156 weeks of treatment for patients in both monotherapy and MTX combination use. No new safety signals were observed.

Filgotinib is an investigational agent and is not approved by the U.S. Food and Drug Administration, European Medicines Agency, or any other regulatory authority. Its efficacy and safety have not been established. For information about the clinical trials with filgotinib: www.clinicaltrials.gov.

About the FINCH Program[i]

The FINCH Phase 3 program investigated the efficacy and safety of 100 mg and 200 mg filgotinib administered once daily in RA patient populations ranging from methotrexate-naïve (MTX) to biologic-experienced patients. FINCH 1 was a 52-week, randomized, placebo- and adalimumab-controlled trial in combination with 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 12, 24 and 52. FINCH 2 was a 24-week, randomized, placebo-controlled trial in 449 patients who were receiving conventional disease-modifying antirheumatic drugs (cDMARD), and had a prior inadequate response to one or more biological therapies. The primary endpoint was ACR20 at week 12. FINCH 3 was a 52-week, randomized trial in 1,252 MTX-naïve patients to evaluate filgotinib 200 mg alone and filgotinib 100 mg or 200 mg combined with MTX versus MTX alone in MTX-naïve patients. The primary endpoint was ACR20 at week 24. Radiographic progression was also assessed at week 24 and 52 in FINCH 3.

About the DARWIN Program[ii]

DARWIN 3 is an ongoing multi-center, open-label, long-term extension study of the double-blind, placebo-controlled DARWIN 1 and DARWIN 2 Phase 2b trials in patients with moderate to severe RA who showed an inadequate response to methotrexate (MTX). DARWIN 1 (594 patients) evaluated filgotinib plus MTX, with either once- or twice-daily administration and at three daily dose levels. DARWIN 2 (283 patients) evaluated filgotinib as once-daily monotherapy at three dose levels. Both DARWIN 1 and DARWIN 2 achieved the primary endpoints (ACR20). The most common AEs noted in the studies were herpes zoster, infections and malignancy excluding non-melanoma skin cancer.

About the Filgotinib Collaboration[iii]

Galapagos and Gilead entered into a global collaboration for the development and commercialization of filgotinib in inflammatory indications.

The FINCH studies in rheumatoid arthritis are among several clinical trials of filgotinib in inflammatory diseases, which also include 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), the Phase 3 SELECTION trial in ulcerative colitis and the Phase 3 PENGUIN 1 and PENGUIN 2 trials in psoriatic arthritis.

More information about clinical trials with filgotinib can be accessed at: www.clinicaltrials.gov.

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. Galapagos' pipeline comprises Phase 3 through to discovery programs in inflammation, fibrosis, osteoarthritis and other indications. The Company's ambition is to become a leading global biopharmaceutical company focused on the discovery, development and commercialization of innovative medicines.

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 may be unable to complete one or more of such trials in the currently anticipated timelines or at all. 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 September 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.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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[i] FINCH Clinical Program Trial Details: FINCH 1 (NCT02889796); FINCH 2 (NCT02873936); FINCH 3 (NCT02886728)

[ii] DARWIN Clinical Program Trial Details: DARWIN 3 (NCT02065700); DARWIN 2 (NCT01894516); DARWIN 1 (NCT01888874)

[iii] Gilead & Galapagos Filgotinib Clinical Program Trial Details: EQUATOR (NCT03320876); TORTUGA (NCT03117270); DIVERSITY (NCT02914561); SELECTION (NCT02914522); PENGUIN 1 (NCT04115748); PENGUIN 2 (NCT04115839)

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