Gilead and Galapagos to Present New Data on Filgotinib at 2019 ACR/ARP Annual Meeting

October 31, 2019

New analyses from filgotinib clinical development program reinforce the investigational medicine's consistent efficacy and safety profile in the treatment of inflammatory diseases

FOSTER CITY, Calif. & MECHELEN, Belgium--(BUSINESS WIRE)--Oct. 31, 2019-- Gilead Sciences, Inc. (NASDAQ: GILD) and Galapagos NV (Euronext & NASDAQ: GLPG) today announced that new data from across the companies' inflammatory disease research and development program will be presented at the 2019 American College of Rheumatology/Association of Rheumatology Professionals (ACR/ARP) Annual Meeting in Atlanta from November 8-13. The companies will present 20 abstracts at this year's meeting, including key data on the investigational medicine filgotinib in rheumatoid arthritis (RA) and psoriatic arthritis (PsA), as well as real-world RA treatment outcomes and care.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20191031005841/en/

"These latest data add to the growing body of evidence on the potential role of filgotinib in the management of rheumatoid arthritis and other inflammatory diseases," said John Sundy, MD, PhD, Senior Vice President, Inflammation and Respiratory Diseases, Gilead Sciences. "People living with RA may experience long-term symptoms that persist despite currently available treatment options. At Gilead, we are working to help improve the lives of people living with inflammatory conditions and look forward to sharing these latest data at ACR/ARP."

"We are proud to share these latest data at the 2019 ACR/ARP Annual Meeting," said Dr. Walid Abi-Saab, Chief Medical Officer, Galapagos. "These results continue to show the potential for filgotinib in RA for patients who face significant challenges living with this disease. Further, we are particularly excited to embark on the PENGUIN Phase 3 trials in psoriatic arthritis, as filgotinib has the potential to address the important unmet medical need of patients living with this disease."

New Filgotinib Efficacy and Safety Data in Rheumatoid Arthritis

Key presentations include multiple subgroup analyses from the FINCH 2 clinical trial that demonstrate the potential of filgotinib across specific RA populations who have experienced an inadequate response to biologic disease-modifying anti-rheumatic drugs (bDMARDs), including those in this difficult-to-treat population with anemia, thrombocytopenia and leukopenia. Key data will also include pooled safety results from the Phase 3 FINCH program (NCT02889796, NCT02873936, NCT02886728), and safety outcomes from the long-term DARWIN-3 trial (NCT02065700).

- *A Subgroup Analysis of the Efficacy of Filgotinib in Demographic and Clinical Subgroups of Patients with Refractory Rheumatoid Arthritis (Poster, #504, Sunday, Nov. 10; 9:00am)*
- *A Subgroup Analysis of Clinical Efficacy Response and Quality of Life Outcomes from Phase 3 Study of Filgotinib in Patients with Inadequate Response to Biologic DMARDs (Poster, #517, Sunday, Nov. 10; 9:00am)*
- *Effects of Filgotinib on Anemia, Thrombocytopenia and Leukopenia: Results from a Phase 3 Study in Patients with Active Rheumatoid Arthritis and Prior Inadequate Response or Intolerance to Biologic DMARDs (Oral, #2875, Wednesday, Nov. 13; 9:00am)*
- *Pooled Safety Analyses from Phase 3 Studies of Filgotinib in Patients with Rheumatoid Arthritis (Poster, #1329, Monday, Nov. 11; 9:00am)*
- *Rheumatoid Arthritis Treatment with Filgotinib: Week 156 Safety and Efficacy Data from a Phase 2b Open-Label Extension Study (Poster, #550, Sunday, Nov. 10; 9:00am)*

In RA, biomarker research seeks to better characterize the molecular basis of the disease and identify populations that may benefit most from a treatment. Gilead is committed to helping drive forward this emerging area of innovation. Presented data will assess the relationship between a series of RA biomarkers and the therapeutic response of filgotinib.

- *bDMARD-Experienced Filgotinib-Treated Patient Samples Exhibit a Partial Reversion to the Peripheral Molecular Profile of a Demographically Matched Healthy Population (Poster, #45, Sunday, Nov. 10; 9:00am)*
- *Key Inflammatory Biomarkers at Baseline are Associated with Filgotinib Response at Week 12 in Rheumatoid Arthritis Patients with Inadequate Response or Intolerance to Biologic DMARDs (Poster, #46, Sunday, Nov. 10; 9:00am)*
- *A Composite IFN-Based Signature is Associated with a Filgotinib-Specific Clinical Response in bDMARD-Experienced Rheumatoid Arthritis Patients (Poster, #2012, Tuesday, Nov. 12; 9:00am)*

Real-World Treatment Experiences in Rheumatoid Arthritis

In addition to therapeutic innovation, increased understanding of the real-world experiences of patients living with RA is needed. Select data will highlight results from multiple studies focused on the overall burden of RA within the U.S.

- *Treatment Patterns and Persistency Following First Biologic DMARD in Patients with Rheumatoid Arthritis: Real-World Analysis of 2012-2016 U.S. Medicare data (Oral, #953, Sunday, Nov. 10; 4:30pm)*
- *Real-World Evidence: Clinical and Economic Burden of Anemia, Venous Thromboembolism, and Malignancy Among Rheumatoid Arthritis Patients Switching from First Biologic DMARD to Another Treatment in the U.S. (Poster, #204, Sunday, Nov. 10; 9:00am)*
- *Real-World Evidence: Infections Among Rheumatoid Arthritis Patients Switching from First Biologic DMARD to Another*

Treatment in the U.S. (Poster, #1374, Monday, Nov. 11; 9:00am)

Filgotinib in Psoriatic Arthritis

Long-Term Safety with Filgotinib in PsA

It is important to understand the safety profile as well as the durability of response to new therapeutic options across potential indications. Results from a long-term safety analysis evaluating the safety of filgotinib for people with PsA will be presented.

- *Long-Term Safety of Filgotinib in Patients with Psoriatic Arthritis, Week 52 Safety Data from a Phase 2 Open-Label Extension Study (Poster, #1534, Monday, Nov. 11; 9:00am)*

Initiation of PENGUIN Phase 3 Program with Filgotinib in PsA

The efficacy and safety of 100 mg and 200 mg filgotinib once-daily compared to placebo will now be further investigated in the PENGUIN Phase 3 program. PENGUIN 1 (NCT04115748) will compare the efficacy and safety of filgotinib, adalimumab and placebo in approximately 1000 patients with active PsA who are naive to bDMARD therapy. PENGUIN 2 (NCT04115839) will measure efficacy and safety of filgotinib vs placebo in 390 patients with active PsA who have an inadequate response or are intolerant to bDMARD therapy. The primary endpoint of each trial is ACR20 response at week 12, with multiple secondary endpoints on signs and symptoms of PsA up to week 24 in PENGUIN 1, and week 16 in PENGUIN 2.

Filgotinib is an investigational agent and is not approved by the U.S. Food and Drug Administration or any other regulatory authority. Its efficacy and safety have not been established.

For more information, including a complete list of the abstracts being presented at the 2019 ACR/ARP annual meeting, please visit: https://acrabstracts.org.

For information about clinical trials with filgotinib, please visit: 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 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 (NCT02914561) in Crohn's disease (also small bowel and fistulizing Crohn's disease Phase 2 studies), the Phase 3 SELECTION trial (NCT02914522) in ulcerative colitis and the Phase 3 PENGUIN trial in psoriatic arthritis.

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.

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.

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, 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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