Gilead and Galapagos Announce TORTUGA Phase 2 Study of Filgotinib in Ankylosing Spondylitis Achieves Primary Endpoint

September 6, 2018 1:01 AM ET

FOSTER CITY, Calif. & MECHELEN, Belgium--(BUSINESS WIRE)--Sep. 6, 2018-- Gilead Sciences, Inc. (NASDAQ:GILD) and Galapagos NV (Euronext & NASDAQ:GLPG) today announced that the randomized, placebo-controlled Phase 2 TORTUGA study of filgotinib, an investigational, selective JAK1 inhibitor, achieved its primary efficacy endpoint in adults with moderately to severely active ankylosing spondylitis (AS). In the study, patients treated with filgotinib achieved significantly greater improvements in AS Disease Activity Score (ASDAS), the primary endpoint, at Week 12, with a mean change from baseline of -1.5 versus -0.6 for those treated with placebo ($p<0.0001$). More patients receiving filgotinib also achieved an ASAS20 response compared to those treated with placebo (76 percent versus 40 percent, $p<0.0001$).

“People with ankylosing spondylitis face serious pain and disability, and, too often, their disease does not respond adequately to existing therapies,” said John McHutchison, MD, Chief Scientific Officer, Head of Research and Development, Gilead. “These data are encouraging, suggesting filgotinib has the potential to play an important role in addressing this medical need.”

“We are excited to see that filgotinib showed strong activity across a wide range of parameters relevant for ankylosing spondylitis and was well tolerated in TORTUGA, which reinforces previous findings about the activity and tolerability profile of filgotinib in multiple inflammatory conditions,” said Dr. Walid Abi-Saab, Chief Medical Officer at Galapagos.

Adverse events were generally mild or moderate in severity and were reported in an equal proportion of patients in the filgotinib and placebo groups. 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 reported for a patient receiving filgotinib who experienced pneumonia and recovered after hospital-based antibiotic treatment. One patient randomized to filgotinib, with an inherited risk for thrombosis, experienced a non-serious deep venous thrombosis after completing the course of study drug. No deaths, malignancies, hepatic events, opportunistic infections or cases of Herpes zoster were observed in the study.

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

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 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 Ankylosing Spondylitis

AS is a systemic, chronic, and progressive seronegative spondyloarthritis that classically affects the spine and sacroiliac (SI) joints and may progress to spinal fusion, leading to permanent disability. Currently, there is no known cure for AS, but there are treatments and medications available to reduce signs and symptoms and manage pain.

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 TORTUGA trial in ankylosing spondylitis is one of several Phase 2 trials in inflammatory diseases 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 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 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 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 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 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 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 ankylosing spondylitis, 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 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20180905006051/en/

Source: Gilead Sciences, Inc.

Galapagos Contacts
Investors:
Elizabeth Goodwin, +1-781-460-1784
VP IR & Corporate Communications
ir@glpg.com
Paul van der Horst, +31 71 750 6707
Director IR & Business Development
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