



Gilead and Galapagos Report Updated Safety Information for Filgotinib in Rheumatoid Arthritis (RA)

March 28, 2019

-- Pooled Interim Phase 3 FINCH Program Data up to 24 Weeks and Phase 2b DARWIN 3 Long-Term Data Add to Evidence Supporting Filgotinib Safety Profile --

FOSTER CITY, Calif. & MECHELEN, Belgium--(BUSINESS WIRE)--Mar. 28, 2019-- regulated information-- Gilead Sciences, Inc. (NASDAQ: GILD) and Galapagos NV (Euronext & NASDAQ: GLPG) today also announced interim safety information from four studies of the investigational compound filgotinib for the treatment of rheumatoid arthritis (RA). The data include 24 week results of the ongoing Phase 3 FINCH 1, 2, and 3 trials, and updated Week 156 safety data from the Phase 2b DARWIN 3 long term extension study in patients with RA.

Week 24 safety data from the FINCH 1, 2, and 3 studies are aggregated and summarized in the table below. Data from 3,452 patients are reported, including 2,088 patients who received filgotinib.

	Placebo/ csDMARD N= 1039 No. (%)	Adalimumab + MTX 40mg EOW N=325 No. (%)	Filgotinib 100 mg +MTX/csDMARD N=840 No. (%)	Filgotinib 200 mg +MTX/csDMARD N=1038 No. (%)	Filgotinib 200 mg N=210 No. (%)	Filgotinib Total N=2088 No. (%)
Serious infections ^{&}	10 (1.0)	8 (2.5)	13 (1.5)	13 (1.3)	3 (1.4)	29 (1.4)
Herpes zoster ^{&}	4 (0.4)	2 (0.6)	5 (0.6)	6 (0.6)	1 (0.5)	12 (0.6)
DVT/PE ^{&}	3 (0.3)	0 (0)	0 (0)	1 (0.1) ^μ	0 (0)	1 (<0.1)
Death [@]	2 (0.2)	0 (0)	1 (0.1)	3 (0.3)	0 (0)	4 (0.2)
Malignancy excluding NMSC ^{&}	4 (0.4)	1 (0.3)	1 (0.1)	0 (0)	0 (0)	1 (<0.1)
MACE ^{&}	5 (0.5)	1 (0.3)	2 (0.2)	2 (0.2)	1 (0.5)	5 (0.2)

MTX, methotrexate; EOW, every other week; csDMARD, conventional synthetic disease-modifying antirheumatic drug; DVT, deep venous thrombosis; PE, pulmonary embolism; NMSC, non-melanoma skin cancer; MACE, major adverse cardiac events

[&] Treatment-emergent events

^μ Excludes one retinal vein occlusion

[@] All events

The Phase 2b DARWIN 3 long term extension trial initially enrolled 739 patients, who received filgotinib 100 mg twice daily, 100 mg or 200 mg once daily. Safety data are summarized in the table below. Results represent treatment through 156 weeks or longer, and comprise 2,203 patient-years of exposure (PYE) to filgotinib.

	Number of Events (Events per 100 Patient-Years) PYE=2,203
Serious infections	27 (1.2)
Herpes zoster	34 (1.5)
DVT/PE	2 (0.1)
Death	5 (0.2)
Malignancy excluding NMSC	11 (0.5)
MACE	3 (0.1)

DVT, deep venous thrombosis; PE, pulmonary embolism; NMSC, non-melanoma skin cancer; MACE, major adverse cardiac events

"The growing body of evidence from both the DARWIN 3 long-term extension trial combined with the results of the FINCH 1, 2, and 3 trials, represent a larger safety database in a broader population of RA patients, spanning from those who are treatment-naive to those who have failed biologics," said John McHutchison, AO, MD, Chief Scientific Officer, Head of Research and Development, Gilead Sciences.

“The available safety data from the FINCH and DARWIN 3 studies, which together included more than 2,700 patients receiving filgotinib, suggest that filgotinib has the potential to deliver a much needed option for treating people living with RA,” said Dr. Walid Abi-Saab, Chief Medical Officer, Galapagos.

Filgotinib is an investigational agent and not approved anywhere globally. Its efficacy and safety have not been established.

About the FINCH program

The FINCH Phase 3 program is investigating the efficacy and safety of 100 mg and 200 mg filgotinib once daily, in RA patient populations ranging from early stage to biologic-experienced patients. **FINCH 1** is a 52-week, randomized, placebo- and adalimumab-controlled trial in combination with methotrexate (MTX) enrolling 1,759 adult patients with moderately to severely active RA who have had inadequate response to MTX. The primary endpoint is ACR20 at week 12. The trial includes radiographic assessment at weeks 24 and 52. **FINCH 2** was a 24-week, randomized, placebo-controlled trial in 449 patients who were receiving conventional disease-modifying anti-rheumatic drugs (cDMARD), and had a prior inadequate response to one or more biological therapies. The primary endpoint was ACR20 at week 12. **FINCH 3** is a 52-week, randomized trial in 1,252 MTX-naïve patients to study filgotinib in combination with MTX, as well as monotherapy. The primary endpoint is ACR20 at week 24. Radiographic progression is also being assessed.

About the DARWIN 3 program

DARWIN 3 is an ongoing multi-center, open-label, long-term follow-up safety and efficacy trial of subjects who completed either DARWIN 1 or DARWIN 2, which were double-blind, placebo-controlled Phase 2b trials for 24 weeks of treatment in patients with moderate to severe RA who showed an inadequate response to methotrexate. DARWIN 1 (594 patients) evaluated filgotinib as an addition to methotrexate, as once- and twice-daily administration (once-daily and twice-daily dosing, respectively) at three daily dose levels. DARWIN 2 (283 patients) evaluated filgotinib as once-daily monotherapy administration (once-daily dosing) at three dose levels. Both DARWIN 1 and DARWIN 2 achieved the primary endpoints (ACR20).

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

About the Galapagos – Gilead Collaboration

Galapagos and Gilead entered into a global collaboration for the development and commercialization of filgotinib in inflammatory indications. The FINCH studies are among several clinical trials of filgotinib in inflammatory diseases, including 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) 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 Phase 3 through to discovery 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.glpg.com.

This press release contains inside information within the meaning of Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (market abuse regulation).

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 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 that the final safety results from these studies differ materially from those reported in this press release and the possibility of unfavorable results from other 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 Annual Report on Form 10-K for the year ended December 31, 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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