

GILEAD AND GALAPAGOS ANNOUNCE FILGOTINIB MEETS PRIMARY AND ALL KEY SECONDARY ENDPOINTS IN FIRST PHASE 3 STUDY IN RHEUMATOID ARTHRITIS

September 11, 2018

- *Filgotinib 100 mg and 200 mg Doses Achieved Significantly Higher ACR20/50/70 Responses than Placebo in Patients with Active Rheumatoid Arthritis and Prior Inadequate Response to Biologic Agents –*
- *Both Filgotinib Doses also Achieved All Key Secondary Efficacy Endpoints, including Low Disease Activity and Clinical Remission –*
- *Tolerability of Filgotinib was Consistent with Previously Reported Studies –*

Foster City, Calif. and Mechelen, Belgium; September 11, 2018 – Gilead Sciences, Inc. (NASDAQ: GILD) and Galapagos NV (Euronext & NASDAQ: GLPG) today announced that FINCH 2, a global, randomized, placebo-controlled, Phase 3 study of filgotinib, an investigational, selective JAK1 inhibitor, in adults with moderately-to-severely active rheumatoid arthritis and prior inadequate response/intolerance to biologic agents, achieved its primary endpoint in the proportion of patients achieving an American College of Rheumatology 20 percent response (ACR20) at Week 12. Also at Weeks 12 and 24, the proportion of patients achieving ACR50 and ACR70, low disease activity (LDA, DAS28(CRP) ≤ 3.2), and clinical remission (DAS28(CRP) < 2.6) were significantly higher for patients receiving once-daily filgotinib 100 mg or 200 mg compared to patients receiving placebo.

Top-line efficacy data are summarized in the table below.

	Week 12			Week 24		
	Placebo (n=148) [#]	Filgotinib 100 mg (n=153) [#]	Filgotinib 200 mg (n=147) [#]	Placebo (n=148) [#]	Filgotinib 100 mg (n=153) [#]	Filgotinib 200 mg (n=147) [#]
Non-responder imputation						
ACR20 (%)	31.1	57.5***	66.0***	34.5	54.9***	69.4***
ACR50 (%)	14.9	32.0***	42.9***	18.9	35.3**	45.6***
ACR70 (%)	6.8	14.4*	21.8***	8.1	20.3**	32.0***
DAS28(CRP) ≤ 3.2 (Low disease activity) (%)	15.5	37.3***	40.8***	20.9	37.9**	48.3***
DAS28(CRP) < 2.6 (Clinical remission) (%)	8.1	25.5***	22.4***	12.2	26.1**	30.6***

[#]Number of patients randomized to each treatment group and who received at least one dose of study drug ACR20/50/70 represents American College of Rheumatology 20%/50%/70% improvements.

* p <0.05, compared to placebo

** p <0.01, compared to placebo

*** p <0.001, compared to placebo

Filgotinib was generally well-tolerated in the FINCH 2 trial, with no new safety signals compared to those reported in previous trials of filgotinib. Treatment-emergent adverse events and serious adverse events were mostly mild or moderate in severity. Serious adverse events occurred in 3.4, 5.2 and 4.1 percent of the patients in the placebo, 100mg and 200mg groups, respectively. The proportion of patients who discontinued study drug due to treatment-emergent adverse events was also similar across groups. Two cases of uncomplicated herpes zoster were reported in each filgotinib group. Two major adverse cardiovascular events (MACE) were identified, one subarachnoid hemorrhage in the placebo group and one myocardial ischemia in the filgotinib 100 mg group. There was one case of non-serious retinal vein occlusion in the filgotinib 200 mg group and no reports of deep venous thrombosis (DVT) or pulmonary embolism (PE). There were no deaths, malignancies, gastrointestinal perforations, or opportunistic infections, including active tuberculosis.

Detailed findings from the FINCH 2 study will be submitted for presentation at a future scientific conference. “Gilead is committed to the development of new therapies that offer meaningful benefit for people living with rheumatoid arthritis and other serious inflammatory diseases,” said John McHutchison, MD, Chief Scientific Officer, Head of Research and Development, Gilead Sciences. “These initial Phase 3 data support the potential of filgotinib, in combination with select disease modifying drugs, to help patients with active rheumatoid arthritis who do not adequately respond to current biologic disease modifying agents. These data are particularly encouraging as we look ahead to Phase 3 results from the ongoing FINCH 1 and 3 trials, which are exploring filgotinib in other populations of patients with rheumatoid arthritis.”

“We are pleased that filgotinib has demonstrated significantly improved clinical responses in this difficult to treat population,” said Dr. Walid Abi-Saab, Chief Medical Officer at Galapagos. “The good tolerability in this study is also very encouraging.”

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 FINCH 2

FINCH 2 was a global, 24-week randomized, double-blind, placebo-controlled, Phase 3 study evaluating filgotinib on a background of conventional synthetic disease-modifying anti-rheumatic drug(s) (csDMARDs) among adult patients with moderately-to-severely active rheumatoid arthritis who had not adequately responded to biologic DMARDs (bDMARDs). In this study, 23.7 percent of patients had received three or more bDMARDs. Patients were randomized (1:1:1) to receive filgotinib 100 mg, filgotinib 200 mg or placebo. The primary endpoint was the proportion of patients achieving an ACR20 response at week 12. Protocol-defined non-responders at Week 14 were allowed to complete the trial under standard of care therapy. Treatment-emergent adverse events are those reported during treatment or within 30 days of the last dose of study drug. For information about clinical trials with filgotinib: 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. Along with FINCH 1 and 3, the Phase 3 FINCH 2 trial is one of several clinical trials of filgotinib in rheumatoid arthritis or other 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) 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.glp.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.

For more information on Gilead Sciences, please visit the company's China website at www.gileadchina.com, or follow Gilead on WeChat by scanning the QR code below:

