

GILEAD AND GALAPAGOS ANNOUNCE POSITIVE TOPLINE RESULTS OF PHASE 2B/3 TRIAL OF FILGOTINIB IN MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS

-- Filgotinib 200 mg Demonstrated Greater Efficacy Compared with Placebo in the Induction and Maintenance of Remission in the SELECTION Trial --

-- Rates of Adverse Events Were Low and Comparable Across Treatment Groups --

Foster City, Calif., and Mechelen, Belgium, May 20, 2020, 22.01 CET; regulated information – Gilead Sciences, Inc. (Nasdaq: GILD) and Galapagos NV (Euronext & Nasdaq: GLPG) today announced positive topline results from SELECTION, a randomized, double-blind, placebo-controlled, Phase 2b/3 trial evaluating the efficacy and safety of the investigational, oral, once-daily, selective JAK1 inhibitor filgotinib in 1,348 biologic-naïve or biologic-experienced adult patients with moderately to severely active ulcerative colitis (UC). Filgotinib 200 mg achieved all primary endpoints in the study, inducing clinical remission at Week 10 and maintaining clinical remission at Week 58 in a significantly higher proportion of patients compared with placebo. Filgotinib 100 mg did not achieve statistically significant clinical remission at Week 10.

In this trial, clinical remission was defined as an endoscopic subscore of 0 or 1, rectal bleeding subscore of 0, and ≥ 1 point decrease in stool frequency from baseline to achieve a subscore of 0 or 1. Among the biologic-naïve cohort (Cohort A induction trial; n=659), 52 percent of patients had a baseline Mayo Clinic Score (MCS) of nine or higher. In the biologically-experienced cohort (Cohort B induction trial; n=689), 74 percent of patients had a baseline MCS of nine or higher, and 51 percent were previously treated with two different classes of biologics (TNF α antagonists and an integrin receptor antagonist).

Among biologic-naïve patients, a statistically significant higher proportion of patients achieved clinical remission at Week 10 when treated with filgotinib 200 mg (26.1 percent, p=0.0157) compared with placebo (15.3 percent). Among biologic-experienced patients, a statistically significant higher proportion of patients achieved clinical remission at Week 10 when treated with filgotinib 200 mg (11.5 percent, p=0.0103) compared with placebo (4.2 percent).

Patients who achieved clinical response or remission after 10 weeks of treatment with filgotinib 100 mg or 200 mg were subsequently re-randomized to their induction dose of filgotinib or placebo in a 2:1 ratio and treated through Week 58 (maintenance trial, n=558). Both doses of filgotinib achieved the primary endpoint in this maintenance trial. At Week 58, 37.2 percent of biologic-naïve and biologic-experienced patients receiving filgotinib 200 mg achieved clinical remission, compared with 11.2 percent treated with placebo (p<0.0001).

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Of patients receiving filgotinib 100 mg, 23.8 percent achieved clinical remission at Week 58, compared with 13.5 percent treated with placebo (p=0.0420).

In the induction trial of biologic-naïve patients, the incidence of serious adverse events was similar across treatment groups (200 mg: 1.2 percent; 100 mg: 4.7 percent; placebo: 2.9 percent). In the induction trial of biologic-experienced patients, the incidence of serious adverse events was also similar across treatment groups (200 mg: 7.3 percent; 100 mg: 5.3 percent; placebo: 6.3 percent). There were no deaths in either induction cohort.

In the maintenance trial, 4.5 percent of patients treated with filgotinib 200 mg experienced a serious

adverse event, compared with none for their corresponding placebo; 4.5 percent of patients treated with filgotinib 100 mg experienced a serious adverse event, compared with 7.7 percent for their corresponding placebo.

Rates of serious infections, herpes zoster, venous thrombosis, pulmonary embolism and gastrointestinal perforation were low and comparable across treatment groups in both the induction and maintenance phases of the study. Two deaths were observed in the filgotinib 200 mg treatment group in the maintenance trial. One patient with pre-existing asthma died due to asthma exacerbation, and the second patient with pre-existing atherosclerosis died due to left ventricular heart failure per autopsy report. Neither death was assessed as related to study drug by the investigator.

“We are encouraged by the early response as an induction therapy and the durable efficacy as a maintenance therapy observed in the SELECTION trial,” said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. “Patients with moderate to severe ulcerative colitis can struggle to effectively manage their disease. These topline data suggest that filgotinib could play a role in helping more patients achieve a meaningful and sustained improvement in treatment response with an oral therapy.”

“We are pleased to see that SELECTION results indicate that filgotinib can help ulcerative colitis patients, including those refractory to treatment, achieve and sustain remission for more than one year,” said Dr. Walid Abi-Saab, Chief Medical Officer, Galapagos. “We believe that the results point to an efficacy and safety profile consistent with prior studies with filgotinib, and offer a meaningful contribution to the patient data with filgotinib from other inflammatory conditions. We look forward to presenting more detailed results to the scientific community.”

UC is a chronic, idiopathic inflammatory disease affecting the colon and often involves periods of remission interspersed with periods of active disease. Common symptoms of UC are bloody diarrhea and rectal urgency. UC is often diagnosed in people of working age who can face debilitating flares in their symptoms and progression of disease overtime. An estimated 40 percent of patients experience a relapse annuallyⁱ and do not achieve sustained remission.

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

Filgotinib is an investigational agent and is not approved by the FDA or any other regulatory authority for any use. Regulatory submissions of filgotinib for the treatment of rheumatoid arthritis are currently under review by the FDA, European Medicines Agency, and Japan’s Ministry of Health, Labour and Welfare. The efficacy and safety of filgotinib have not been established. For information about the clinical trials with filgotinib: www.clinicaltrials.gov.

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About the SELECTION Phase 2b/3 Trial

The SELECTION Phase 2b/3 trial is a multi-center, randomized, double-blind, placebo-controlled trial to assess the safety and efficacy of the selective JAK1 inhibitor filgotinib in adult patients with moderately to severely active ulcerative colitis. The SELECTION trial comprises 2 Induction Trials and a Maintenance Trial. The Cohort A Induction Trial enrolled biologic-naïve patients, and the Cohort B Induction Trial enrolled biologic-experienced patients.

Across both induction studies, patients with moderately to severely active UC were randomized to receive filgotinib 200 mg, filgotinib 100 mg or placebo in a 2:2:1 ratio. Moderately to severely active UC was defined as a centrally read endoscopy score ≥ 2 , a rectal bleeding score ≥ 1 , a stool frequency score ≥ 1 and

Physician Global Assessment (PGA) of ≥ 2 based on the MCS. Patients with clinical remission or response at Week 10 of induction were subsequently re-randomized to the induction dose of filgotinib or placebo in a 2:1 ratio and treated through Week 58.

The primary objectives of SELECTION are to evaluate the efficacy of filgotinib compared with placebo in establishing EBS clinical remission as determined by the Mayo Clinic endoscopic subscore of 0 or 1, rectal bleeding subscore of 0, and ≥ 1 point decrease in stool frequency from baseline to achieve a subscore of 0 or 1 at Week 10 and Week 58. Eligible patients who completed treatment in the SELECTION trial through Week 58 were enrolled in the ongoing SELECTION long-term extension trial to evaluate the long-term safety of filgotinib in patients with moderately to severely active UC.

About the Filgotinib Collaborationⁱⁱ

Gilead and Galapagos are collaborative partners in the global development and commercialization of filgotinib in inflammatory indications. The SELECTION trial is one of multiple clinical studies of filgotinib in a range of inflammatory conditions, including the FINCH Phase 3 program in rheumatoid arthritis, the DIVERSITY Phase 3 trial in Crohn's disease, the Phase 3 PENGUIN trials in psoriatic arthritis, as well as Phase 2 studies in uveitis and in small bowel and fistulizing Crohn's disease. More information about clinical trials with filgotinib can be accessed at www.clinicaltrials.gov.

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.

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 discovery through Phase 3 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).

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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 for the treatment of ulcerative colitis and other inflammatory diseases and the possibility that the parties may be unable to complete such trials in the currently anticipated timelines or at all. Further, the regulatory submissions of filgotinib for the treatment of rheumatoid arthritis that are currently under review by the FDA, European Medicines Agency and Japan's Ministry of Health, Labour and Welfare may not be approved in the currently anticipated timelines or at all, and any marketing approvals, if granted, may have significant limitations on its use. It is also 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 Form 10-Q for the quarter ended March 31, 2020, 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.

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.

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ⁱ McMullan, C. et al. BMJ Open 2017: Adapting to ulcerative colitis to try to live a ‘normal’ life. Available at: <https://bmjopen.bmj.com/content/bmjopen/7/8/e017544.full.pdf>. Accessed May 2020.

ⁱⁱ Gilead & Galapagos Filgotinib Clinical Program Trial Details: FINCH 1 ([NCT02889796](#)); FINCH 2 ([NCT02873936](#)); FINCH 3 ([NCT02886728](#)); SELECTION ([NCT02914522](#)); DIVERSITY ([NCT02914561](#)); PENGUIN 1 ([NCT04115748](#)); PENGUIN 2 ([NCT04115839](#))