Galapagos announces new data supporting rapid symptom improvement and sustained steroid-free remission with filgotinib in patients with Ulcerative Colitis

New post-hoc analyses of data from SELECTION Phase 3 program presented at European Crohn's and Colitis Organisation (ECCO) virtual congress

Mechelen, Belgium; 10 July 2021, 11.10 CET; Galapagos NV (Euronext & NASDAQ: GLPG) today announced new post-hoc analyses from the Phase 3 SELECTION program, supporting the activity and tolerability of filgotinib, a once-daily, oral JAK1 preferential inhibitor, under investigation for the treatment of patients with moderately to severely active ulcerative colitis (UC). These data were presented at the European Crohn's and Colitis Organisation (ECCO) 16th annual congress.

A *post-hoc* analysis of the induction study data from SELECTION showed significant improvements in patient-reported outcomes (PROs) of stool frequency (SF) and of rectal bleeding (RB), that were observed as early as the first week of therapy in patients on 200mg of filgotinib daily versus placebo in patients with moderately to severely active UC. These findings were observed in both biologic-naïve and biologic-experienced patients. More patients receiving filgotinib 200mg versus placebo achieved a composite score of RB=0 and SF≤1 as early as day 9 in Induction study A (biologic-naïve; filgotinib 200mg 18.8%, placebo 9.5%, $p<0.05$) and as early as day 7 in Induction study B (biologic-experienced; filgotinib 200mg 10.7%; placebo 4.2%, $p<0.05$). [1]

A further *post-hoc* analysis of the SELECTION maintenance study reported the proportion of patients who were steroid-free at different timepoints, before achieving remission at Week 58. These data indicated that filgotinib 200mg reduced and eliminated corticosteroid (CS) use versus placebo at Week 58 in patients with moderately to severely active UC. Compared with placebo, a significantly higher proportion of patients who demonstrated CS-free remission at Week 58 with filgotinib 200mg had been CS-free in the previous six months (27% filgotinib 200mg vs 6% placebo, 95% CI 21 (8, 34), with a difference seen from as early as the previous eight months (22% filgotinib 200mg vs 6% placebo, 95% CI 15 (3, 28)). [2]

Additional safety analysis from SELECTION, combining induction, maintenance and the long-term extension study data, with a cumulative treatment exposure of 1,207 patient years for filgotinib 200mg versus 318 patient years for placebo, showed results consistent with the original induction and maintenance trials, where filgotinib was well tolerated in patients with moderately to severely active UC.[3]

Walid Abi-Saab, Chief Medical Officer at Galapagos stated, "Listening to the needs of patients living with moderately and severely active UC, and the healthcare professionals treating them, helps us understand the importance of finding treatments that address both clinical symptoms and patient reported outcomes. These new data from SELECTION and the long-term extension study suggest that patients with moderately to severely active UC have experienced rapid response, sustained steroid-free remission and long-term tolerability when taking filgotinib 200mg versus those on a placebo".

About Ulcerative Colitis
Ulcerative colitis (UC) is a chronic type of inflammatory bowel disease (IBD) that occurs as a result of an abnormal immune system response. Across Europe an estimated 2 million people[4] are affected by IBD, which includes UC and Crohn's Disease (CD). It is a chronic inflammatory condition of the gastrointestinal (GI) tract. The disease course of UC is often a state of flare ups and ensuing periods of remission. In addition to the physical impact from flare ups, there is also a significant psychological impact associated with UC, which is further compounded by the perceived stigma of the condition.

About the SELECTION Phase 3 Trial
The SELECTION Phase 3 trial is a multi-center, randomized, double-blind, placebo-controlled trial to assess the safety and efficacy of the preferential JAK1 inhibitor filgotinib in adult patients with moderately to severely active UC. The SELECTION trial comprises two induction trials and a maintenance trial. The Induction Study A enrolled biologic-naïve patients, and the Induction Study B enrolled biologic-experienced patients.

Across both induction studies, 1348 patients with moderately to severely active UC were randomized to receive either filgotinib 200mg, filgotinib 100mg 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 Mayo Clinic Score (MCS). 644 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 were to evaluate the efficacy of filgotinib compared with placebo in establishing clinical remission as determined by the Mayo 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 in the induction studies and Week 58 in the maintenance study. Eligible patients who were enrolled in the SELECTION trial 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. A majority of patients included in the trials had a MCS of 9 or higher at baseline, and 43% of biologic experienced patients had insufficient response to a TNF antagonist and vedolizumab as well.

For SELECTION study information visit: https://clinicaltrials.gov/ct2/show/NCT02914522

About filgotinib
Filgotinib is approved and marketed as Jyseleca (200mg and 100mg tablets) in the European Union, Great Britain, and Japan for the treatment of adults with moderate to severe active rheumatoid arthritis (RA) who have responded inadequately or are intolerant to one or more disease modifying anti-rheumatic drugs (DMARDs). Filgotinib may be used as monotherapy or in combination with methotrexate (MTX). The European Summary of Product Characteristics for filgotinib, which includes contraindications and special warnings and precautions, is available at www.ema.europa.eu. The interview form from the Japanese Ministry of Health, Labour and Welfare is available at www.info.pmda.go.jp. The Great Britain and Northern Ireland Summary of Product Characteristics is available at www.medicines.org.uk/emc. Applications have been submitted to the European Medicines Agency (EMA), the UK's Medicines and Healthcare products Regulatory Agency (MHRA), and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) for the treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response

with, lost response to, or were intolerant to either conventional therapy or a biologic agent and are currently under review. Filgotinib is not approved in any other countries.

About the filgotinib collaboration
Gilead and Galapagos NV are collaborative partners in the global development and commercialization of filgotinib. Galapagos will be responsible for the commercialization of filgotinib in Europe (transition anticipated to be completed by end of 2021), while Gilead will remain responsible for filgotinib outside of Europe, including in Japan, where filgotinib is co-marketed with Eisai. Filgotinib in UC has been filed in Europe, the UK and Japan, and a global Phase 3 program is ongoing in Crohn's Disease. More information about clinical trials can be accessed at https://www.clinicaltrials.gov

About Galapagos
Galapagos NV discovers, develops, and commercializes small molecule medicines with novel modes of action, several of which show promising patient results and are currently in development in multiple diseases. Our pipeline comprises discovery through Phase 3 programs in inflammation, fibrosis and other indications. Our ambition is to become a leading global biotech company focused on the discovery, development and commercialization of innovative medicines. More information at www.glpg.com.
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1. Danese. S, et al. Rapidity of symptom improvements during filgotinib induction therapy in patients with Ulcerative Colitis: *post hoc* analysis of the phase 2b/3 SELECTION study. OP37, ECCO Congress 2021
2. Loftus, E, et al. Corticosteroid-free remission of Ulcerative Colitis with filgotinib maintenance therapy: post hoc analysis of the phase 2b/3 SELECTION study DOP82, ECCO Congress 2021
3. Schreiber. S, et al. Safety analysis of filgotinib for Ulcerative Colitis: results from the phase 2b/3 SELECTION study and phase 3 SELECTIONLTE long-term extension study. OP04, ECCO Congress 2021
4. Burisch J. et al. The burden of inflammatory bowel disease in Europe. *Journal of Crohn's and Colitis* (2013) 7, 322-337

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Forward Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, that are subject to risks, uncertainties and other factors that could cause actual results to differ materially from those referred to in the forward-looking statements and, therefore, the reader should not place undue reliance on them. These risks, uncertainties and other factors include, without limitation, the inherent risks associated with clinical trial and product development activities, including the SELECTION study, competitive developments, and regulatory approval requirements, including the risk that the results of the SELECTION study may not support continued approval of Jyseleca for the treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent due to safety, efficacy or other reasons , the timing or likelihood of regulatory authorities approval of marketing authorization for filgotinib for UC or any other indications, such regulatory authorities requiring additional studies, Galapagos' reliance on collaborations with third parties, including the collaboration with Gilead for filgotinib, Galapagos' estimations regarding its filgotinib development program and regarding the commercial potential of filgotinib, risks related to the implementation of the transition of the European commercialization responsibility to us, as well as those risks and uncertainties identified in our Annual Report on Form 20-F for the year ended 31 December 2020 and our subsequent filings with the SEC. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The forward-looking statements contained herein are based on management's current expectations and beliefs and speak only as of the date hereof, and Galapagos makes no commitment to update or publicly release any revisions to forward-looking statements in order to reflect new information or subsequent events, circumstances or changes in expectations.