

SELECTION study on filgotinib in ulcerative colitis published in *The Lancet*

Mechelen, Belgium; 4 June 2021; 07.01 CET; – Galapagos NV (Euronext & Nasdaq: GLPG) today announced that primary and secondary endpoint results from the phase 3 SELECTION induction and maintenance study (NCT02914522) were published in *The Lancet* (doi.org/10.1016/S0140-6736(21)00666-8). The study, sponsored by Gilead Sciences, Inc., was designed to assess the efficacy and safety of the once-daily, oral preferential JAK1 inhibitor, filgotinib, under investigation in patients with moderately to severely active ulcerative colitis (UC).

In addition to the primary and secondary endpoints, which have been reported at the United European Gastroenterology congress in October 2020 and can be found on the Galapagos website, www.glpg.com/press-releases, the publication also reports data from a post-hoc analysis by induction cohort of filgotinib 200mg versus placebo during the maintenance study on multiple efficacy endpoints. These include sustained clinical remission, 6-month corticosteroid free remission, Mayo Clinic Score (MCS), endoscopic and histologic remission, MCS response and endoscopic improvement. Across all these endpoints, numerically greater differences in favor of filgotinib 200mg compared to placebo were shown. This is reported independent of previous biologic treatment status (biologic-naïve and biologic-experienced) with an overall larger numerical effect among biologic-naïve patients¹.

A further post-hoc analysis in the publication reports mucosal healing, a composite endpoint defined as endoscopic improvement (Mayo endoscopy score 0-1) and histological remission in the same patient. The proportion of patients achieving mucosal healing after 10 weeks of induction treatment with filgotinib 200mg was numerically greater compared with placebo (23.3% vs 10.9% in biologic-naïve and 9.9% vs 4.2% in biologic-experienced) and at week 58 in the overall study population (32.7% vs 10.2%)².

Dr. Walid Abi-Saab, Chief Medical Officer at Galapagos said, "Achieving early and sustained remission from symptoms, combined with mucosal healing are key goals of therapy in ulcerative colitis. These analyses suggest a positive treatment effect on a range of measures, including mucosal healing, across a broad patient population, which includes those who have failed conventional therapy as well as those who have failed previous biologics."

The incidence of adverse events (AEs), serious adverse events (SAEs) and discontinuations due to AEs were similar in the filgotinib and placebo groups in both the induction and maintenance periods of the study. In the induction studies, SAEs occurred in 4.7%, 5.0% and 4.3% of patients who received placebo, filgotinib 100mg and 200mg respectively. In the maintenance study, SAEs were experienced by 4.5% of patients in the filgotinib 100mg group and 7.7% in the respective placebo group and by 4.5% of patients in the filgotinib 200mg group and no patients in the respective placebo group. Exposure adjusted incidence rates of SAEs were similar across treatment groups in the induction and maintenance studies. Two deaths were observed in the filgotinib 200mg treatment group in the maintenance trial; both adverse events leading to deaths were considered by the study investigators as unrelated to study drug.

UC is a long-term condition characterized by inflammation of the mucosal lining of the colon and rectum. As an increasingly prevalent disease, UC has a significant impact on the quality of life of

more than 2 million people across Europe. Despite current treatments, many patients experience fecal urgency, incontinence, recurring bloody diarrhea, and the need to empty their bowels frequently, often accompanied by abdominal pain, poor sleep, and fatigue.

The use of filgotinib for UC is investigational and not approved anywhere globally. Its efficacy and safety have not been established.

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.

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 score of 9 or higher at baseline, and 43% of biologic experienced patients had insufficient response to a TNF antagonist and vedolizumab as well.

Data on the primary endpoint showed that a greater proportion of biologic-naïve and biologic-experienced patients receiving filgotinib 200mg achieved clinical remission at Week 10 than those on placebo (26.1% versus 15.3% $p=0.0157$ and 11.5% versus 4.2% $p=0.013$ respectively). This clinical remission was maintained up to 58 weeks for those receiving filgotinib 200mg versus those receiving placebo (37.2% versus 11.2% $p<0.001$). The difference for filgotinib 100mg was not statistically significant in the induction study, however in the maintenance study at Week 58 a statistically significant difference was seen versus placebo (23.8% versus 13.5%, $p=0.0420$).

Overall, the incidence of adverse events (AEs), serious AEs and discontinuations due to AEs were similar in the filgotinib and placebo groups in both the induction and maintenance periods of the study, as reported above.

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

For access to SELECTION in The Lancet publication visit;

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00666-8/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00666-8/fulltext)

¹ Feagan. B., et al: Filgotinib as induction and maintenance therapy for ulcerative colitis: the SELECTION trial. The Lancet [https://doi.org/10.1016/S0140-6736\(21\)00666-8](https://doi.org/10.1016/S0140-6736(21)00666-8). Appendix page 29, Table S4

² Feagan. B., et al: Filgotinib as induction and maintenance therapy for ulcerative colitis: the SELECTION trial. The Lancet [https://doi.org/10.1016/S0140-6736\(21\)00666-8](https://doi.org/10.1016/S0140-6736(21)00666-8). Appendix page 15, Figure S5

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 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 and Japan a global Phase 3 program is ongoing in Crohn's Disease. More information about clinical trials can be accessed at 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 late-stage 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.glpq.com.

Contacts

Investors:

Elizabeth Goodwin
VP Investor Relations
+1 781 460 1784

Sofie Van Gijssels
Senior Director Investor Relations
+32 485 19 14 15
ir@glpg.com

Media:

Carmen Vroonen
Global Head of Communications & Public Affairs
+32 473 824 874

Anna Gibbins
Senior Director Therapeutic Areas Communications
+44 7717 801900
communications@glpg.com

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, competitive developments, and regulatory approval requirements, including the risk that data from the ongoing and planned clinical research programs with filgotinib may not support registration or further development in UC or other indications 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, the uncertainty regarding estimates of the commercial potential of filgotinib, the timing of and the risks related to completing and implementing the amendment of our arrangement with Gilead for the commercialization and development of Jyseleca (filgotinib), 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.