

Galapagos provides further insights into the treatment of ulcerative colitis at the European Crohn's and Colitis Organization (ECCO) annual congress

- *Nine presentations demonstrate Galapagos' commitment to inflammation and the ulcerative colitis (UC) community*
- *Four new analyses from Phase 3 SELECTION and SELECTION long term extension studies of Jyseleca® (filgotinib) provide additional insights into the management of ulcerative colitis (UC)*
- *Initial results from European real-world survey investigating the disease burden, including residual disease symptoms and quality of life*

Mechelen, Belgium; 2 February 2022, 22.01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) will present data at the European Crohn's and Colitis Organization (ECCO) annual congress taking place 16-19 February 2022. Nine oral and poster presentations will be showcased, including four new analyses from the phase 3 SELECTION and SELECTION long term extension (LTE) studies. These are part of the clinical program assessing the efficacy and safety of Jyseleca (filgotinib), an oral, once-daily, JAK1 preferential inhibitor, for the treatment of patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent. In addition, insights from patients participating in a European real-world survey on the disease burden of UC will be presented.

"At Galapagos, we believe taking a holistic approach to the management of ulcerative colitis is incredibly important and can make a real difference for people living with this disease," said Dr. Walid Abi-Saab, Chief Medical Officer, Galapagos. "Our commitment to understanding what matters most for patients with UC and finding ways to better treat this often debilitating disease, is reflected in the wide range of new data we are presenting at ECCO."

The new analyses provide further evidence of the efficacy and safety profile of filgotinib 200mg, when used in appropriate patients for the treatment of UC:

- Holistic assessment of disease and reporting of subjective measures alongside objective measures can be equally important in setting treatment goals to improve outcomes in UC. In this novel post-hoc analysis of the SELECTION program a combined composite endpoint, including clinical, biological, health related quality of life (HRQoL) remission and endoscopic improvements was assessed for patients treated with filgotinib (100mg and 200mg) versus placebo.
- In the SELECTION study, filgotinib 200mg was well tolerated and efficacious at inducing and maintaining clinical remission versus placebo in patients with ulcerative colitis¹. This interim analysis of SELECTION LTE assesses the efficacy and safety outcomes of long-term treatment with filgotinib 200mg, up to 96 weeks.
- Long-term treatment regimens in UC can present challenges for patients who may need to interrupt therapy for various reasons². A post-hoc analysis of the SELECTION and SELECTION LTE studies was undertaken to evaluate the efficacy and safety of re-treatment with filgotinib, following treatment interruption.

- There is a clinical need to understand the impact of treatment in elderly patients, where there is a growing prevalence of inflammatory bowel disease (IBD)³. This post-hoc analysis of data from the SELECTION program evaluates the efficacy and safety of filgotinib, stratified by age.

In addition to the clinical data, Galapagos will present initial results from a European real-world survey investigating the disease burden, including residual disease symptoms and quality of life impairment in moderate to severe UC patients in remission and not in remission.

Oral and poster presentations

Abstract Title	Authors	Presentation Date/Time
Exploring disease control by combining clinical, biological, and health-related quality of life remission with endoscopic improvements among Ulcerative Colitis patients treated with filgotinib: A post-hoc analysis from the SELECTION trial	<u>Stefan Schreiber</u> , Brian Feagan, Laurent Peyrin-Biroulet, Severine Vermeire, Margaux Faes, Kristina Harris, Alessandra Oortwijn, Patrick Daniele, Haridarshan Patel and Silvio Danese	Oral presentation: OP07 Date: 17 February 2022 Session: Navigating the Oceans of IBD - Scientific Session 3: Aiming high with treatment goals in IBD: The modern Icarus? Session time: 16:00 – 17:20 CET Presentation time: 16:40 – 16:50 CET
Efficacy and safety of filgotinib in patients with Ulcerative Colitis stratified by age: Post hoc analysis of the phase 2b/3 SELECTION and SELECTION LTE studies	<u>Stefan Schreiber</u> , <u>Edward V Loftus Jr</u> , Christian Maaser, Silvio Danese, Christine Rudolph, Rob Jongen, Angela De Haas, Alessandra Oortwijn and Séverine Vermeire	Digital Oral presentation: DOP37 Date: 17 February 2022 Session: DOP Session 5: The Southern: Small molecules in IBD Session time: 17:30 – 18:30 CET Presentation time: 17:30 – 17:36 CET
Re-treatment with filgotinib in patients with Ulcerative Colitis following treatment interruption: Analysis of the SELECTION and SELECTION LTE studies	<u>Séverine Vermeire</u> , Brian Feagan, Laurent Peyrin-Biroulet, Alessandra Oortwijn, Margaux Faes, Angela de Haas and Gerhard Rogler	Poster: P517 Date: 18 February 2022 Session: Guided poster session Poster discussion session: 12:30 – 13:30 CET
Efficacy and safety outcomes of long-term treatment with filgotinib 200 mg among patients with Ulcerative Colitis: An interim analysis of SELECTIONLTE	<u>Brian Feagan</u> , Katsuyoshi Matsuoka, Gerhard Rogler, Margaux Faes, Alessandra Oortwijn, Angela de Haas, Christine Rudolph, Haridarshan Patel and Laurent Peyrin-Biroulet	Poster: P491 Date: 18 February 2022 Session: Guided poster session Poster discussion session: 12:30 – 13:30 CET
Rates of clinical remission among patients with Ulcerative Colitis	<u>Bernd Bokemeyer</u> , Nils Picker, Daniel Kromer,	Poster: P506 Date: 18 February 2022

from real-world clinical practice settings from Germany	Ludger Rosin and Haridarshan Patel	Session: Guided poster session Poster discussion session: 12:30 – 13:30 CET
Indicators for inadequate response among patients with Ulcerative Colitis treated with advanced therapies in German clinical practice	<u>Bernd Bokemeyer</u> , Nils Picker, Daniel Kromer, Ludger Rosin and Haridarshan Patel	Poster: P598 Date: 18 February 2022 Session: Guided poster session Poster discussion session: 12:30 – 13:30 CET
Indicators for inadequate response to advanced therapy in patients with Ulcerative Colitis: results from a medical chart review in the United Kingdom	<u>James Oliver Lindsay</u> , Nils Picker, Daniel Kromer, Michael Smyth and Haridarshan Patel	Poster: P389 Date: 18 February 2022 Session: Guided poster session Poster discussion session: 12:30 – 13:30 CET
Insights from patients with Ulcerative Colitis on disease burden: Findings from a real-world survey in Europe	<u>Johan Michael Burisch</u> , Ailsa Hart, Alessandra Oortwijn, Javaria Mona Khalid, Fritha Hennessy, Hannah Knight, Rachael Meadows, Haridarshan Patel and Alessandro Armuzzi	Poster: P293 Date: 18 February 2022 Session: Guided poster session Poster discussion session: 12:30 – 13:30 CET

About Ulcerative Colitis

Ulcerative colitis (UC) is a debilitating inflammatory bowel disease (IBD) that occurs as a result of an abnormal immune system response. Across Europe an estimated 2.5 - 3 million people⁴ are affected by IBD, which includes UC and Crohn’s Disease (CD). UC is a chronic inflammatory condition characterized by periods of flare ups followed by remission. In addition to the physical impact from flare ups, there is also a psychological impact associated with UC. It causes significant impairments on quality of life and a poor prognosis is often seen in patients with symptoms of moderate to severe UC at diagnosis.

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 UC¹. 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 UC. A majority of patients included in the SELECTION trial (n=1348) had a Mayo Clinic Score (MCS) score of 9 or higher at baseline, and 43% of biologic experienced patients (n=297/689) had insufficient response to a TNF antagonist and vedoluzimab as well.

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). Filgotinib is also approved and marketed as Jyseleca (200mg and 100mg tablets) in the European Union and Great Britain for the treatment of adult patients with moderately to severely active UC who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent. An application has been submitted to the Japan's Pharmaceuticals and Medical Devices Agency (PMDA) for the treatment of adults with moderately to severely active UC and is currently under review. The European Summary of Product Characteristics for filgotinib, which includes contraindications and special warnings and precautions, is available at www.ema.europa.eu. The Great Britain Summary of Product Characteristics for filgotinib can be found at www.medicines.org.uk/emc and the Northern Ireland Summary of Product Characteristics for filgotinib can be found at www.emcmedicines.com/en-GB/northernireland. The interview form from the Japanese Ministry of Health, Labour and Welfare is available at www.info.pmda.go.jp. A global Phase 3 program with filgotinib is ongoing in Crohn's Disease. More information about clinical trials can be accessed at <https://www.clinicaltrials.gov>.

Jyseleca® is a trademark of Galapagos NV and Gilead Sciences, Inc. or its related companies.

About the filgotinib collaboration

Gilead and Galapagos NV are collaborative partners in the global development and commercialization of filgotinib. Galapagos is responsible for the commercialization of filgotinib in Europe, while Gilead will remain responsible for filgotinib outside of Europe, including in Japan, where filgotinib is co-marketed with Eisai.

About Galapagos

Galapagos NV discovers, develops, and commercializes small molecule medicines with novel modes of action. Our pipeline comprises discovery through Phase 3 programs in inflammation, fibrosis, 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.glpag.com.

1. Feagan BF et al. *Lancet* (2021); 397:2372–84.
2. Rubin DT. *Gastroenterol Hepatol* (2019); 15 :612-5
3. Zammarchi et al. *BMG Gastroenterol* (2020); 20 :147
4. Burisch J. et al. *Journal of Crohn's and Colitis* (2013); 7:322-337

Contact

Investors:

Sofie Van Gijssel
Senior Director Investor Relations
+1 781 296 1143

Sandra Cauwenberghs
Director Investor Relations
+32 495 58 46 63
ir@glpg.com

Media:

Anna Gibbins
Senior Director Therapeutic Areas Communications
+44 7717 801900

Marieke Vermeersch
Head of Corporate Communication
+32 479 490 603
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, including the filgotinib clinical program and the SELECTION Phase 3 trial, the inherent uncertainties associated with competitive developments, 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 or efficacy concerns or other reasons), the timing or likelihood of regulatory authorities approval of marketing authorization for filgotinib for other indications, such regulatory authorities requiring additional studies, the risk that Galapagos will not be able to continue to execute on its currently contemplated business plan and/or will need to revise its business plan, Galapagos' reliance on collaborations with third parties (including our collaboration partner for filgotinib, Gilead) and that Galapagos' estimations regarding its filgotinib development program, regarding the commercial potential of filgotinib and regarding the out roll in Europe may be incorrect and, the uncertainties relating to the impact of the COVID-19 pandemic on our strategy, business plans and focus, 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.