

Galapagos provides further insights into the treatment of ulcerative colitis at the upcoming United European Gastroenterology (UEG) Week 2022 congress

- Five presentations demonstrate Galapagos' commitment to inflammation and the ulcerative colitis (UC) community
- New analyses will be presented from the SELECTION data set on prediction of response and remission, histology data and trajectory model
- Presentation on safety data of filgotinib in enriched risk population in rheumatoid arthritis

Mechelen, Belgium; 6 October 2022, 22.01 CET, Galapagos NV (Euronext & NASDAQ: GLPG) will present data at the United European Gastroenterology (UEG) Week 2022, taking place from 8-11 October 2022. Several Galapagos driven presentations will be showcased, including new *post hoc* analyses of the SELECTION study, which investigated the safety and efficacy of Jyseleca® (filgotinib), an oral, once-daily, JAK1 preferential inhibitor, in patients with moderately to severely active UC.

Dr Walid Abi-Saab, Chief Medical officer of Galapagos said, "We continue to analyze data from the different studies of filgotinib in patients with UC to inform and empower healthcare professionals to make the most appropriate choices for patients. We are committed to making a real difference to patients by finding ways to better treat this debilitating condition and are excited to share these data and insights at the UEG Week."

In addition to clinical data presentations, Galapagos is also hosting a hybrid symposium: **'JAK to the future – a patient centric choice in UC'** on Monday 10 October 2022, which will feature experts' perspectives on taking a patient-centric, comprehensive approach to disease control as the best approach to address current unmet needs in UC management and on how the JAK class can help HCPs navigate the current and future treatment landscape.

Scientific Abstracts:

Title	Authors	Presentation date/time
Galapagos-driven abstracts		
Trajectory modelling to identify different types of individual response to therapy: a <i>post hoc</i> analysis from the SELECTION study	Stefan Schreiber , Laurent Peyrin-Biroulet, Toshifumi Hibi, Louis Dron, Sichen Liu, Claus A. Andersen, Alessandra Oortwijn, Haridarshan Patel, Brian Feagan	Poster Number: MP443 Date: Tuesday, October 11, 14:00–15:00 Presentation time: 14:12 – 14:18 (6 min incl. 3 min discussion) Session: Response prediction in IBD - Moderated Poster
Predictors of response to filgotinib in ulcerative colitis: <i>post hoc</i> analysis from the SELECTION study	Brian Feagan , Laurent Peyrin-Biroulet, Edouard Louis, Virginia Taliadouros, Franck-Olivier Le Brun, Alessandra Oortwijn, Haridarshan Patel, Angela de Haas, Tadakazu Hisamatsu	Poster Number: MP447 Date: Tuesday, October 11, 14:00–15:00 Presentation time: 14:36 – 14:42 (6 min incl. 3 min discussion) Session: Response prediction in IBD - Moderated Poster

<p>Use of faecal calprotectin as a prognostic marker of response to treatment with filgotinib: <i>post hoc</i> analysis from the SELECTION study</p>	<p>Edouard Louis, Brian Feagan, Tadakazu Hisamatsu, Virginia Taliadouros, Rob Jongen, <u>Alessandra Oortwijn</u>, Carole Van der Donckt, Laurent Peyrin-Biroulet</p>	<p>Poster Number: P0353 Date: Sunday, October 9, 08:00–19:30 Session: E-Poster Session - Science Lounge <i>On-site poster round: Monday, October 10, 12:30-13:30 Terminal 20: Lower GI</i></p>
<p>Assessment of histological remission in patients treated with filgotinib by different scores and concordance with endoscopic and health-related quality of life outcomes: <i>post hoc</i> analysis from the SELECTION study</p>	<p><u>Fernando Magro</u>, Laurent Peyrin-Biroulet, Gerhard Rogler, Alessandra Oortwijn, Haridarshan Patel, Angela de Haas, Eva Santermans, Haoyao Ruan, Louis Dron, Brian Feagan</p>	<p>Poster Number: P0488 Date: Sunday, October 9, 08:00–19:30 Session: E-Poster Session - Science Lounge <i>On-site poster round: Tuesday, October 11, 12:30-13:30 Terminal 21: Lower GI</i></p>
<p>Exploratory analysis of filgotinib safety data in a selected population of patients with rheumatoid arthritis: data from FINCH 1–4 and DARWIN 1–3 studies in perspective to integrated ulcerative colitis safety data</p>	<p>Stefan Schreiber, Maya H. Buch, Xavier Mariette, Gerd R. Burmester, Christina Charles-Schoeman, Vijay Rajendran, Nadia Verbruggen, Agustin Cerani, Paul Van Hoek, Katrien Van Beneden, <u>Alessandra Oortwijn</u>, Yoshiya Tanaka, Ennio Giulio Favalli, Hendrik Schulze-Koops, René Westhovens, Severine Vermeire</p>	<p>Poster Number: P0418 Date: Sunday, October 9, 08:00–19:30 Session: E-Poster Session - Science Lounge</p>

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 people¹ 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 study

The SELECTION Phase 3 study is a multi-center, randomized, double-blind, placebo-controlled study to assess the safety and efficacy of the preferential JAK1 inhibitor filgotinib in adult patients with moderately to severely active UC. The SELECTION study (NCT02914535) 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 sub-score of 0, and ≥ 1 -point decrease in stool frequency from baseline to achieve a sub-score 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 study were enrolled in the ongoing

¹ Burisch J. et al. Journal of Crohn’s and Colitis (2013); 7:322-337.

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 study (n=1348) had a Mayo Clinic Score (MCS) 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. (Feagan et al., *Lancet* 2021; 397: 2372–84)

About filgotinib

Filgotinib is marketed as Jyseleca (200mg and 100mg tablets) in the European Union (incl. Norway), Great Britain, and Japan for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have responded inadequately or are intolerant to one or more disease modifying anti-rheumatic drugs (DMARDs). Filgotinib is also marketed as Jyseleca (200mg tablets) in the European Union (incl. Norway), Great Britain, and Japan for the treatment of adult 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. 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>.

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, respectively. The interview form from the Japanese Ministry of Health, Labour and Welfare is available at www.info.pmda.go.jp.

Jyseleca® is a trademark of Galapagos NV and Gilead Sciences, Inc. or its related companies. Except for filgotinib's approval as Jyseleca for the treatment of moderately to severely RA and UC by the relevant regulatory authorities in the European Union, Great Britain, and Japan, our drug candidates are investigational; their efficacy and safety have not been fully evaluated by any regulatory authority.

About Galapagos

Galapagos is a fully integrated biotechnology company focused on discovering, developing, and commercializing innovative medicines. We are committed to improving patients' lives worldwide by targeting diseases with high unmet needs. Our R&D capabilities cover multiple drug modalities, including small molecules and cell therapies. Our portfolio comprises discovery through to Phase 4 programs in inflammation, oncology, fibrosis, and other indications. Our first medicine for rheumatoid arthritis and ulcerative colitis is available in the European Union, Norway, Great Britain, and Japan. For additional information, please visit www.glp.com or follow us on [LinkedIn](#) or [Twitter](#).

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Forward Looking Statements

This press release includes forward-looking statements, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "may," "upcoming," "future," "potential," "will," and "plan," as well as similar expressions. Forward-looking statements contained in this release include, but are not limited to, statements regarding Galapagos' plans and strategy with respect to Jyseleca and the DARWIN, SELECTION, and FINCH studies. Any forward-looking statements in this release are based on Galapagos management's current expectations and beliefs and are not guarantees of future performance. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause Galapagos' actual results, performance or achievements to be materially different from any historic or future results, performance or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and other factors include, without limitation, the risk that ongoing and future clinical studies with filgotinib may not be completed in the currently envisaged timelines or at all, the inherent risks associated with clinical trial and product development activities, including the filgotinib clinical program and the DARWIN, SELECTION, and FINCH studies, the inherent risks and 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, including but not limited to the data from the ongoing DARWIN, SELECTION, and FINCH studies, may not support registration or further development of filgotinib due to safety, efficacy or other reasons), the risks related to continued regulatory review of filgotinib following approval by relevant regulatory authorities, including EMA's safety review of JAK inhibitors used to treat certain inflammatory disorders, the risks that regulatory authorities may require additional post-approval trials of filgotinib or any other product candidates that are approved in the future, Galapagos' reliance on collaborations with third parties (including our collaboration partner for filgotinib, Gilead) and that Galapagos' estimations regarding its filgotinib development program and regarding the commercial potential of filgotinib may be incorrect, 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, and risks related to the ongoing COVID-19 pandemic, as well as those risks and uncertainties identified in our most recent Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (SEC), as supplemented and/or modified by any other filings and reports that we have made or will make with the SEC in the future. Given these risks and uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. In addition, even if Galapagos' results, performance or achievements are consistent with such forward-looking statements, they may not be predictive of results, performance or achievements in future periods. These forward-looking statements speak only as of the date of publication of this release. Galapagos expressly disclaims any obligation to update any such forward-looking statements in this release unless required by law or regulation.