Galapagos to present new data from long-term extension study of filgotinib in ulcerative colitis at annual ECCO congress 2023

- Six presentations demonstrate Galapagos' commitment to the inflammatory bowel disease (IBD) community
- New analyses from Phase 3 SELECTION and SELECTION long-term extension (LTE) studies of Jyseleca® (filgotinib, an oral, once daily, JAK1 preferential inhibitor) will be presented
- SELECTIONLTE showed that filgotinib maintained a consistent safety profile; symptomatic remission rates and health-related quality of life (HRQoL) improved in patients with moderate to severe active ulcerative colitis (UC) who received filgotinib 200mg for nearly four years

Mechelen, Belgium; 27 February 2023, 22.01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) will present new data at the European Crohn's and Colitis Organization (ECCO) annual congress taking place from 1-4 March 2023.

A number of abstracts will present analyses from the SELECTION program with filgotinib. These include new analysis from the long-term extension study evaluating the safety and efficacy of filgotinib in UC for nearly four years; an analysis of the prolonged benefit of filgotinib in UC; an analysis exploring factors associated with the partial Mayo Clinic Score (pMCS) over time; and analysis of the effect of filgotinib on anaemia in UC patients.

Additionally, Galapagos will present pooled data from five Phase 2/3 trials, and two long-term extension trials of filgotinib designed to further understand the safety profile of filgotinib in UC and rheumatoid arthritis (RA).

"We are excited to present data from multiple studies of filgotinib in UC, including results from the SELECTIONLTE study, which has been selected amongst the top 11 oral abstracts at ECCO," said Daniele D'Ambrosio, MD, PhD, Therapeutic Area Head, of Immunology, at Galapagos. "These presentations capture our broad range of research and commitment to the IBD community and underscore our mission to improve patients' lives by targeting diseases with high unmet needs."

Data from the SELECTIONLTE study showed that filgotinib 200mg maintained symptomatic remission and HRQoL for up to approximately four years. Amongst subjects who completed the study, the reduction in mean pMCS in SELECTION was maintained up to LTE Week 144. In non-responders, mean pMCS decreased from LTE baseline to Week 192. The results also showed that a high proportion of completers (>80% of patients) and non-responders (>70% of patients) achieved remission according to the Inflammatory Bowel Disease Questionnaire[1].

The safety profile of filgotinib 200mg in the SELECTIONLTE study was generally consistent with the safety profile observed in previous SELECTION studies, with no new safety signals observed.

"For healthcare professionals treating patients with this debilitating disease, the results from the SELECTION studies provide an understanding of filgotinib's long-term outcomes and help make the most appropriate choices for their patients," said Dr. Brian G. Feagan, MD, FRCPC, Professor of Medicine, Epidemiology and Biostatistics, Western University, London, Ontario, Canada and lead investigator of the SELECTION trial. "This latest data reinforces the positive long-term safety and efficacy profile of filgotinib, indicating its potential to be an important treatment option for people living with moderate to severe UC."

Galapagos is also hosting a hybrid symposium: ***'Journey to comprehensive disease control in UC'*** on Thursday 2 March 2023 from 18:45-19:45 CET, which will feature experts' perspectives on what matters most to patients, and how to raise the bar when treating patients with UC. The symposium will include a mix of classical plenary lectures, including tackling challenges and misconceptions, sharing of real-world practical experience in the management of patients with UC, and the place of JAK inhibition in clinical practice.

[1] The Inflammatory Bowel Disease Questionnaire is a widely used questionnaire for HRQoL assessment in patients with inflammatory bowel diseases.

Key Abstracts:

Abstract title	Authors	Presentation date/time
Efficacy and safety outcomes up to ~4 years of treatment with filgotinib 200mg among patients with Ulcerative Colitis: Results from the SELECTION LTE study	Brian Feagan, Katsuyoshi Matsuoka, Gerhard Rogler, Margaux Faes, Alessandra Oortwijn, Angela de Haas, Christine Rudolph and Laurent Peyrin-Biroulet	**Oral presentation** **Presentation number:** OP35 **Presentation date, time & location:** Saturday 4 March 2023, 09:50-10:00, Plenary Hall **Session name:** Sequencing in IBD - Scientific Session 10: Evolving goals
Prolonged benefit of filgotinib in patients with Ulcerative Colitis in SELECTION	David Laharie, Andreas Sturm, Taku Kobayashi, Takayuki Matsumoto, Alessandra Oortwijn, Corinne Jamoul, Margaux Faes, Angela de Haas and Séverine Vermeire	**Poster presentation** **Presentation number:** P690 **Presentation date, time & location:** Friday 3 March 2023, 12:30-13:30, Poster Exhibition, Hall B5&6
Factors associated with partial Mayo Clinic Score over time in patients with Ulcerative Colitis treated with filgotinib in the phase 2b/3 SELECTION trial	Laurent Peyrin-Biroulet, Edouard Louis, Tadakazu Hisamatsu, Corinne Jamoul, Eva Santermans, Kristina Harris, Angela de Haas, Alessandra Oortwijn and Brian Feagan	**Poster presentation** **Presentation number:** P736 **Presentation date, time & location:** Friday 3 March 2023, 12:30-13:30, Poster Exhibition, Hall B5&6
Effect of filgotinib on anaemia in patients with Ulcerative Colitis in SELECTION	Roberta Loveikyte, Angela de Haas, Alessandra Oortwijn, Bart Eskens, Corinne Jamoul, Karine Muller and Andrea E. van der Meulen-de Jong	**Poster presentation** **Presentation number:** P393 **Presentation date, time & location:** Friday 3 March 2023, 12:30-13:30, Poster Exhibition, Hall B5&6
Thromboembolic and major adverse cardiovascular events among patients in the filgotinib clinical trial programme	C Janneke van der Woude, Stefan Schreiber, Laurent Peyrin-Biroulet, Zoltán Szekanecz, Ernest HS Choy, Pieter-Jan Stiers, Paul Van Hoek, Katrien Van Beneden, Angela de Haas, Christine Rudolph and Hugo ten Cate	**Poster presentation** **Presentation number:** P520 **Presentation date, time & location:** Friday 3 March 2023, 12:30-13:30, Poster Exhibition, Hall B5&6
Investigating the symptom burden among European patients with moderate-to-severe Crohn's disease using a real-world survey	Johan Burisch, Ailsa Hart, Andreas Sturm, Hannah Knight, Christine Rudolph, Rachael Meadows, Alessandra Oortwijn, Sarah Weatherby, Roger Rolph, Fatima Dawod and Alessandro Armuzzi	**Poster presentation** **Presentation number:** P624 **Presentation date, time & location:** Friday 3 March 2023, 12:30-13:30, Poster Exhibition, Hall B5&6

About 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 people[2] 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 clinical program
The SELECTION program comprised of SELECTION and the associated long-term extension study (SELECTIONLTE).

The SELECTION Phase 3 study was a multi-center, randomized, double-blind, placebo-controlled study designed to assess the safety and efficacy of the preferential JAK1 inhibitor filgotinib in adult patients with moderate to severe active UC. The SELECTION study (NCT02914522) comprised of two induction trials and a maintenance trial. Induction Study A enrolled biologic-naïve patients and Induction Study B enrolled biologic-experienced patients. A majority of the patients included in the SELECTION study (n=1348) had a pMCS of 9 or higher at baseline, and 43% of biologic-experienced patients (n=297/689) had an insufficient response to a TNF antagonist and vedolizumab as well.[3]

The primary objectives of the SELECTION clinical program were to evaluate the efficacy of filgotinib compared with a placebo in establishing clinical remission as determined by the Mayo endoscopic sub-score, rectal bleeding sub-score, and decrease in stool frequency from baseline. Patients who completed the induction and maintenance studies, patients who were not responders at Week 10, and patients with disease worsening during the maintenance study were enrolled in the ongoing SELECTIONLTE study (NCT02914535) to evaluate the long-term safety and efficacy of filgotinib in patients suffering from UC. An interim report of SELECTIONLTE assessed the safety and efficacy of open-label filgotinib through to Week 144 in completers and through to Week 192 in non-responders, respectively.

About filgotinib
Filgotinib is marketed as Jyseleca® in Europe and Japan for the treatment of adults with moderate to severe active RA who have responded inadequately or are intolerant to one or more disease modifying anti-rheumatic drugs. Filgotinib is also marketed as Jyseleca® in Europe and Japan for the treatment of adult patients with moderate to severe active UC who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent. Jyseleca® 100mg and 200mg applications are registered in the above-mentioned territories.

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 moderate to severe active 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

[2] Burisch J. et al. *Journal of Crohn's and Colitis* 2013; 7:322-337.

[3] Feagan et al., *Lancet* 2021; 397: 2372–84.

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 commercialized programs in immunology, oncology, and other indications. Our first medicine for rheumatoid arthritis and ulcerative colitis is available in Europe and Japan. For additional information, please visit www.glpg.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 "will," "further," "prolonged," "ongoing," "estimated," "over time," "long-term," and "consistent," as well as similar expressions. Forward-looking statements contained in this press release include, but are not limited to, statements related to our plans and strategy with respect to the SELECTION and SELECTIONLTE study, statements related to the data and the analysis of data from the SELECTION and SELECTIONLTE study, and statements related to our plans and strategy with respect to filgotinib. We caution the reader that forward-looking statements are based on our management's current expectations and beliefs and are not guarantees of our future performance. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause our actual results, performance or achievements to be materially different from any historic or future results, performance or achievements expressed or implied by such 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 and uncertainties associated with competitive developments, clinical trials, recruitment of patients, product development activities, and regulatory approval requirements (including, without limitation, 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), including the filgotinib clinical program and the SELECTION and SELECTIONLTE study, the risks related to continued regulatory review of filgotinib following approval by relevant regulatory authorities, including the European Medicines Agency'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 of our other product candidates that may be approved in the future, our reliance on collaborations with third parties (including Gilead), the risk that our estimations regarding our filgotinib development program and the commercial potential of filgotinib may be incorrect, the risk that we will not be able to continue to execute on our currently contemplated business plan and/or will need to revise our business plan, and risks related to the ongoing COVID-19 pandemic. A further list and description of these risks, uncertainties, and other risks can be found in our filings and reports with the U.S. Securities and Exchange Commission ("SEC"), including in our most recent annual report on Form 20-F filed with the SEC and our subsequent filings and reports filed with the SEC. Given these risks and uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. In addition, even if our 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. We expressly disclaim any obligation to update any such forward-looking statements in this press release unless required by law or regulation.