

## Galapagos presents new data from the SELECTION Phase 3 program at the United European Gastroenterology Week (UEGW) 2021 congress

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- *Continuing filgotinib 200mg among induction non-responders at week 10 resulted in clinical benefits for ulcerative colitis (UC) patients in the long-term extension study (LTE)*
- *Treatment with filgotinib 200mg resulted in clinically meaningful improvements in health-related quality of life (HRQoL) measures by week 58 among patients with UC*

**Mechelen, Belgium; 4 October 2021, 22.01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) today announced results of two post-hoc analyses from the SELECTION and SELECTION LTE studies, which are part of the investigational clinical program for filgotinib, for the treatment of patients with moderately to severely active UC. These analyses showed clinical benefits of continued dosing with filgotinib 200mg, an oral once-daily JAK1 preferential inhibitor, in patients who did not respond at week 10. Separately, HRQoL benefits of filgotinib 200mg treatment versus placebo, in patients with UC were shown. These data will be presented at the UEGW virtual 2021 congress (3 – 5 October).**

In SELECTION, patients who did not respond to induction therapy at week 10 could receive open-label filgotinib in the LTE. In a post-hoc analysis, it was shown that continuing filgotinib 200mg among those non-responders resulted in 65.7% biologic-naïve and 62.2% biologic-experienced patients achieving partial Mayo Clinic Score (pMCS) response by Week 12, with 17.1% biologic-naïve and 16.7% biologic-experienced patients in pMCS remission (Presentation MP082).<sup>1</sup>

A post-hoc analysis of HRQoL data from the SELECTION study shows that patients treated with filgotinib 200mg achieved clinically meaningful improvements in their quality of life, versus placebo. These included Inflammatory Bowel Disease Questionnaire remission and measurements of productivity, physical, and mental components, assessed by 36-item Short Form Survey (SF-36), EuroQol 5-dimension (EQ-5D) visual analogue scale and Work Productivity and Activity Impairment questionnaire (Poster PO457).<sup>2</sup>

Dr Walid Abi-Saab, Chief Medical officer, at Galapagos said, “The SELECTION study has provided us with a wealth of data on the efficacy and safety profile of filgotinib that, if approved can potentially inform clinical treatment approaches. This includes findings on the benefits of prolonged dosing with filgotinib 200mg among induction non-responders and the achievement of treatment goals beyond clinical symptoms of UC. We know that patients with UC are impacted by this disease physically, socially and psychologically, which is why inclusion of health-related quality of life measures in our clinical trials is so important to build a holistic understanding of the management of the disease.”

These data were in two of thirteen abstracts from the company relating to filgotinib in the treatment of patients with UC. The use of filgotinib for the treatment of UC is investigational and is not approved anywhere globally.

### Key Filgotinib Abstracts:

Abstract Title	Lead Author	Poster number and time and date
Benefit of prolonged filgotinib dosing in patients with ulcerative colitis who did not respond to induction therapy: data from the SELECTION long-term extension study	Séverine Vermeire	<b>Moderated poster presentation</b> <ul style="list-style-type: none"> <li>• Presentation number: <b>MP082</b></li> <li>• Session: IBD: Clinical trials poster II</li> <li>• Date: Monday 4 October 2021, 13:30–14:30 CET</li> </ul>
Clinically meaningful improvements in health-related quality of life among patients	William J Sandborn	<b>Poster presentation</b>

with ulcerative colitis treated with filgotinib – a post hoc analysis of SELECTION		<ul style="list-style-type: none"> <li>• Presentation number: <b>P0457</b></li> <li>• Poster Session: IBD</li> <li>• Date: Sunday 3 – Tuesday 5 October</li> </ul>
A Matching-Adjusted Indirect Comparison of Maintenance Oral Filgotinib versus Intravenous Vedolizumab for Moderately to Severely Active Ulcerative Colitis	Xiaoyan Lu	<b>Poster presentation</b> <ul style="list-style-type: none"> <li>• Presentation number: <b>P0489</b></li> <li>• Poster Session: IBD</li> <li>• Date: Sunday 3 – Tuesday 5 October</li> </ul>
Efficacy of filgotinib in patients with ulcerative colitis by line of therapy in the phase 2b/3 SELECTION trial	Laurent Peyrin-Biroulet	<b>Oral presentation</b> <ul style="list-style-type: none"> <li>• Presentation number: <b>OP191</b></li> <li>• Session: IBD clinical trials IV</li> <li>• Session Type: Live Abstract-based Session</li> <li>• Date: Tuesday 5 October 2021 13:30–14:30 CEST</li> </ul>
Relationship between histo-endoscopic mucosal healing and baseline characteristics in patients with moderately to severely active ulcerative colitis receiving filgotinib in the phase 2b/3 SELECTION study	Laurent Peyrin-Biroulet	<b>Poster presentation</b> <ul style="list-style-type: none"> <li>• Presentation number: <b>P0427</b></li> <li>• Poster session: IBD</li> <li>• Date: Sunday 3 – Tuesday 5 October</li> </ul>

### 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 people<sup>3</sup> are affected by IBD, which includes UC and Crohn's Disease (CD). UC 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 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 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  $\geq 1$ -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 had a MCS score of 9 or higher at baseline, and 43% of biologic experienced patients had insufficient response to a TNF antagonist and vedoluzimab as well.

### About HRQoL and IBDQ

Health-related quality of life (HRQoL) is a concept that measures physical, emotional, mental, and social impact of the disease on patients' lives. The instruments used to measure HRQoL were a 36-item Short Form Survey (SF-36), EuroQol 5-dimension visual analogue scale (EQ-5D-VAS) and Work, Productivity and Activity Impairment (WPAI) questionnaire, and Inflammatory Bowel Disease Questionnaire (IBDQ).

The IBDQ is a questionnaire for health-related quality of life assessment in patients with inflammatory bowel diseases: ulcerative colitis and Crohn's disease. It consists of 32 questions divided into four groups: bowel symptoms (10 items), systemic symptoms (5 items), emotional function (12 items) and social function (5 items). Every question has graded responses from 1 to 7, and thus the total score can range from 32 to 224 with higher scores representing better health-related quality of life. IBDQ remission was defined by an IBQ

total score  $\geq 170$  points. The IBDQ is a validated assessment tool that reflects important changes in the quality of life of patients with IBD (adapted from Pallis et al, *Inflamm Bowel Dis*, Volume 10, Number 3, May 2004).

SF-36 is a generic health-assessment questionnaire that is utilized in clinical trials to study the impact of chronic disease on health-related quality of life.

EQ-5D is a general, non-disease-specific health-related quality-of-life questionnaire.

WPAI is a tool used to measure the impact of a disease on work and on daily activities.

### About filgotinib

Filgotinib is approved and marketed as Jyseleca<sup>®</sup> (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](http://www.ema.europa.eu). The interview form from the Japanese Ministry of Health, Labour and Welfare is available at [www.info.pmda.go.jp](http://www.info.pmda.go.jp). The individual Great Britain and Northern Ireland Summary of Product Characteristics can be found at [www.medicines.org.uk/emc](http://www.medicines.org.uk/emc) and [www.emcmedicines.com/en-GB/northernireland](http://www.emcmedicines.com/en-GB/northernireland) respectively. 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 (UC) 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. A positive opinion was recommended for this UC indication by the EMA's Committee for Medicinal Products for Human Use (CHMP) on 17th September. Filgotinib is not approved in any other countries.

*Jyseleca<sup>®</sup> 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 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 the European Union, Great-Britain 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. 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.glpg.com](http://www.glpg.com).

1. Vermeire, S, et al. Benefit of prolonged filgotinib dosing in patients with ulcerative colitis who did not respond to induction therapy: data from the SELECTION long-term extension study: post hoc analysis of the phase 2b/3 SELECTION study MP082, UEGW Congress 2021
2. Sandborn, W, et al. Clinically meaningful improvements in health-related quality of life among patients with ulcerative colitis treated with filgotinib: post hoc analysis of the phase 2b/3 SELECTION study. P0457, UEGW Congress 2021
3. 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 filgotinib clinical program, 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, 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 the collaboration with Gilead for filgotinib, the uncertainty regarding estimates of the commercial potential of filgotinib, the timing of and the risks related to the implementation of the transition of the European commercialization responsibility of filgotinib from Gilead to us, including the risk that the transition will not be completed on the currently contemplated timeline or at all, and the risk that the transition will not have the currently expected results for our business and results of operations; 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.