

Jyseleca[®]▼ (filgotinib) approved in the European Union for the treatment of ulcerative colitis

Mechelen, Belgium; 15 November 2021; 16.45 CET; Galapagos NV (Euronext & Nasdaq: GLPG) announced today that the European Commission has granted marketing authorization for Jyseleca[®] (filgotinib 200mg tablets) for the treatment of adult patients with moderately to severely active ulcerative colitis (UC).

The European Commission approved an additional indication for Jyseleca, an oral, once-daily, JAK1 preferential inhibitor, for 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. The Commission based its decision on data from the Phase 2b/3 SELECTION program, which evaluated filgotinib as an induction and maintenance therapy in the patient population now included in the label. The SELECTION trial was published in *The Lancet*[†].

“We are very pleased that the European Commission has approved Jyseleca as a treatment for people with UC. This decision further supports the efficacy and safety profile of Jyseleca, which was studied in over 1,250 UC patients. Our focus now is on making this treatment available as rapidly as possible to physicians and UC patients across the European Union,” said Onno van de Stolpe, CEO of Galapagos.

Professor Laurent Peyrin-Biroulet, Professor of Gastroenterology and Head of the Inflammatory Bowel Disease (IBD) group at the Gastroenterology Department, University Hospital of Nancy, France, and Principal Investigator for the SELECTION study, said: “Despite available treatments for managing UC, there is still a need for new and innovative therapies like Jyseleca. UC is an incurable and disabling disease; in severe cases we aim to keep patients out of hospital and reduce the need for surgical procedures such as colectomies. Overall, our goals are to manage the symptoms that have a significant, negative impact on a person’s overall well-being, to be able to stop the use of steroids and to improve the daily life of patients. In the SELECTION study we observed filgotinib’s tablet form was easily administered, provided significantly greater corticosteroid-free clinical remission from symptoms compared to placebo and was well tolerated by patients.”

UC is a life-long condition commonly starting in late adolescence or early adulthood and characterized by inflammation of the mucosal lining of the colon and rectum. As an increasingly prevalent disease, UC has a significant negative impact on the quality of life of more than 2 million² people across Europe. Despite current treatments, many patients experience faecal urgency, incontinence, recurring bloody diarrhea, the need to empty their bowels frequently, abdominal pain, poor sleep, and fatigue. Patients with severe UC can be hospitalized and require life changing surgery. In addition to the physical symptoms, there is also a significant psychological impact associated with UC.

Luisa Avendano, CEO at the European Federation of Crohn’s and Ulcerative Colitis Associations (EFCCA) said: “The impact that living with UC can have on a person’s life cannot be underestimated. It is important for each individual to speak to their doctor about what approach will work best to help them manage their condition. Having new approved treatment choices is therefore very important, and at EFCCA we are pleased to see new options being made available.”

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 tablets) in the European Union 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. 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 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. Applications have been submitted to 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 UC and are currently under review. 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>. Filgotinib is not approved in any other countries.

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 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.

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.glp.com.

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).
2. 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, RA, Crohn's disease or other indications 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 the collaboration with Gilead for filgotinib, the risk that Galapagos estimations regarding the commercial potential of filgotinib may be incorrect, 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.