

## **JYSELECA®▼ (FILGOTINIB) LICENSED FOR THE TREATMENT OF ADULT PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS IN GREAT BRITAIN**

**Mechelen, Belgium; 18 January 2022; 22.01 CET; Galapagos NV (Euronext & Nasdaq: GLPG) announced today that the Medicines and Healthcare products Regulatory Agency (MHRA) has granted a marketing authorization for Jyseleca® (filgotinib 200mg tablets), as a new treatment for ulcerative colitis (UC) for Great Britain.**

The MHRA has licensed an additional indication for Jyseleca, an oral once-daily, JAK1 preferential inhibitor, for use in 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 submission was supported by data from the Phase 2b/3 SELECTION program, published in *the Lancet*<sup>1</sup>. The decision from the MHRA follows authorisation from the European Commission (EC) for use in the same patient population.

Michele Manto, Chief Commercial Officer at Galapagos said: "At Galapagos we are committed to bringing new and innovative medicines to healthcare professionals who are treating patients with UC and today we are one step closer to offering a new treatment option to thousands of patients living in Great Britain with UC, a chronic and debilitating disease. Together with the EC decision, this decision represents an important milestone in our plans to make Jyseleca available to eligible adult patients with UC across Europe."

Dr Ian Beales, Consultant in Gastroenterology and General Medicine, Norfolk and Norwich University Hospital and Chief Investigator for the SELECTION study in the UK said: "The prevalence of UC in the UK is increasing. 1 in every 420 people are currently estimated to have the disease. Despite available treatments there is still a need for innovative new therapies to provide relief from the symptoms that can have debilitating physical consequences for patients. In the SELECTION study when compared to placebo, more patients on filgotinib 200mg demonstrated corticosteroid-free remission from clinical symptoms with improvements in measures of health-related quality of life and was well-tolerated by patients. We welcome having a new treatment option available to help us with managing this disease."

UC is a life-long condition characterized by inflammation of the mucosal lining of the colon and rectum. Current estimates suggest that in the UK more than 146,000<sup>2</sup> people are currently living with UC. The prevalence of inflammatory bowel diseases, which includes UC, is rising in the UK with peak diagnosis in late adolescence or early adulthood<sup>3</sup>.

Ruth Wakeman, Director of Services, Advocacy & Evidence, Crohn's & Colitis UK, said: "Ulcerative Colitis can be an extremely debilitating condition, affecting many parts of the body and many aspects of life. It can affect people in very individual ways, so effective and appropriate treatment based on personalized care and shared decision making is really important. For some people with UC, existing treatments may not work, so additional treatment options are welcome."

### **About filgotinib**

Filgotinib is licensed and marketed as Jyseleca (200mg and 100mg tablets) in Great Britain, the European Union 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 licensed and marketed as Jyseleca in Great Britain and the

European Union for the treatment of adult patients with moderately to severely active ulcerative colitis 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 Great Britain Summary of Product Characteristics for filgotinib can be found at [www.medicines.org.uk/emc](http://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](http://www.emcmedicines.com/en-GB/northernireland). 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). 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 remains 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.glpq.com](http://www.glpq.com).

1. Feagan. B., et al: Filgotinib as induction and maintenance therapy for ulcerative colitis: The SELECTION trial. The Lancet. 2021. [https://doi.org/10.1016/S0140-6736\(21\)00666-8](https://doi.org/10.1016/S0140-6736(21)00666-8)
2. Ulcerative colitis. NHS (2021). Available at: <https://www.nhs.uk/conditions/ulcerative-colitis/#:~:text=It's%20estimated%20around%201%20in,15%20to%2025%20years%20old> [Accessed: October 2021]
3. Malodecky NA., et al: Increasing incidence and prevalence of inflammatory bowel disease with time, based on a systematic review. Gastroenterology 2012; 142:46-54

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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, Galapagos' estimations regarding the outroll in Europe, including in Great Britain, 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.*