# GALAPAGOS ANNOUNCES POSITIVE CHMP OPINION FOR JYSELECA® (FILGOTINIB) FOR THE TREATMENT OF ADULTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS

**Mechelen, Belgium; 17 September 2021; 13.15 CET; Galapagos NV (Euronext & Nasdaq: GLPG) announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for Jyseleca® (filgotinib), a once-daily, oral, JAK1 preferential inhibitor 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. Following this positive opinion, a final decision from the European Commission is expected later this year.**

The CHMP positive opinion is based on data from the pivotal Phase 2b/3 SELECTION program, which evaluated filgotinib as an induction and maintenance therapy in adult patients with moderately to severely active UC who have failed conventional therapy or biologics. SELECTION comprised two placebo-controlled induction studies, one in biologic-naive patients and the other in biologic-experienced patients, followed by a 47-week maintenance study for those who responded to filgotinib after 10 weeks. Responders to placebo continued on blinded placebo during the maintenance phase. The trial was recently published in *The Lancet*[1].

Dr Walid Abi-Saab, Chief Medical Officer at Galapagos, said: "Ulcerative colitis can have significant and profound effects on the people who suffer with the condition. Persistent inflammation and uncontrolled disease mean patients may experience debilitating relapses, may need increasing doses of steroids and in some instances may require surgery, which impacts them not only physically, but also psychologically. Today's decision brings us one step closer to providing a new treatment option for people living with this chronic disease."

The CHMP positive opinion will now be reviewed by the European Commission and a decision is expected before year end 2021. This positive opinion follows the previous approval of filgotinib for the treatment of patients with moderate to severe active rheumatoid arthritis. The use of filgotinib for UC is investigational and is not approved anywhere globally.

**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 million people[2] 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 significant 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 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). 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 individual Great Britain and Northern Ireland Summary

of Product Characteristics can be found at www.medicines.org.uk/emc and 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. 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. Filgotinib in UC has been filed in Europe, 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.


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.
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 forward-looking statements include statements concerning the timing and outcome of a final decision by the European Commission and statements concerning the safety, efficacy and commercial potential of filgotinib. 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, 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, 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.*