

Gilead Sciences submits new drug application in Japan for filgotinib for the treatment of ulcerative colitis with an inadequate response to conventional therapies

Application is based on Phase 2b/3 SELECTION study data with patients with moderately to severely active ulcerative colitis

Mechelen, Belgium; 23 April 2021; 06.01 CET; – Galapagos NV (Euronext & Nasdaq: GLPG) today report that their collaboration partner Gilead Sciences K.K. (“Gilead”) and Eisai Co., Ltd. (“Eisai”) today announced that Gilead submitted an application to Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) for approval of filgotinib for an additional indication to treat patients with moderately to severely active ulcerative colitis (UC). Filgotinib is a new oral Janus kinase (JAK) inhibitor approved in Japan in September 2020 for the treatment of rheumatoid arthritis.

This latest regulatory submission is based on data from the randomized, double-blind, placebo-controlled Phase 2b/3 SELECTION study evaluating the efficacy and safety of filgotinib for the induction and maintenance of remission in 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. This study showed a statistically significant higher proportion of patients treated with filgotinib 200mg once daily achieved clinical remission at week 10 and maintained remission at week 58 compared with placebo. No new safety risks were identified.

Ulcerative colitis is a chronic disease characterized by inflammation of the lining of the mucosa of the colon and rectum. The prevalence of ulcerative colitis has been increasing in recent years, and it has a significant impact on the quality of life of more than 2 million people around the world. Even with treatment, defecation urgency, incontinence, recurrent bloody diarrhea, frequent bowel movements, abdominal pain, insomnia and fatigue are common. Ulcerative colitis is one of the intractable diseases¹ designated by the Ministry of Health, Labour and Welfare in Japan. According to a nationwide survey, the estimated number of patients with ulcerative colitis in Japan in 2014 was 219,685. The annual prevalence rate per 100,000 was 172.9 (192.3 men, 154.5 women).²

About filgotinib

Filgotinib is approved and marketed as Jyseleca (200mg and 100mg tablets) in the Europe Union, Great Britain and Japan for the treatment of adults with moderately to severely 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). This definition from 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 is available at www.medicines.org.uk/emc. Applications have been submitted to the EMA, the MHRA and the PMDA for the treatment of adults 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 and are currently under review. Filgotinib is not approved in any other countries.

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 and Japan and a global Phase 3 program is ongoing in Crohn's Disease. More information about clinical trials can be accessed at www.clinicaltrials.gov.

About Galapagos

Galapagos NV discovers, develops and commercializes small molecule medicines with novel modes of action, several of which show promising patient results and are currently in late-stage development in multiple diseases. Our pipeline comprises discovery through Phase 3 programs in inflammation, fibrosis and other indications. Our ambition is to become a leading global biotech company focused on the discovery, development and commercialization of innovative medicines. More information at www.glpq.com.

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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, 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, statements relating to interactions with the regulatory authorities, Galapagos' strategic R&D ambitions and potential changes of such ambitions, 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 implementing the amendment of our arrangement with Gilead for the commercialization and development of Jyseleca (filgotinib), the uncertainties relating to the impact of the COVID-19 pandemic, 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.

¹Japan promotes research related to intractable diseases and financially supports patients with these diseases. Intractable diseases are designated as those that fulfill the following criteria: (1) rarity (affecting less than 0.1% of the population in Japan), (2) unknown etiology, (3) lack of effective treatment, (4) necessity of long-term treatment, and (5) existence of objective diagnostic criteria and not necessarily equal to rare diseases in other countries. *Neurol Med Chir (Tokyo)*. 2017 Jan; 57(1): 1–7. Published online 2016 Sep 21. doi: 10.2176/nmc.st.2016-0135

²Murakami Y, Nishiwaki Y, Oba MS, Asakura K, Ohfuji S, Fukushima W, et al. Estimated prevalence of ulcerative colitis and Crohn's disease in Japan in 2014: an analysis of a nationwide survey. *J Gastroenterol* 2019;54 (12):1070-7