

Jyseleca® approved in Japan for ulcerative colitis

Approval of additional indication based on Phase 2b/3 SELECTION study in patients with moderate-to-severe ulcerative colitis

Mechelen, Belgium; 28 March 2022, 08.01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) reports that Gilead Sciences K.K. (Tokyo, Japan), Eisai Co., Ltd. (Tokyo, Japan) and EA Pharma Co., Ltd. (Tokyo, Japan) today announced the approval by the Japanese Ministry of Health, Labour and Welfare (MHLW), of a second indication for Jyseleca (filgotinib), a once-daily, oral, JAK1 preferential inhibitor, for the treatment of patients with moderate-to-severe active ulcerative colitis (UC).

The approval of this second indication for Jyseleca in Japan is based on data from the randomized, double-blind, placebo-controlled phase 2b/3 SELECTION study. This study evaluated the efficacy and safety of Jyseleca for induction and maintenance of remission in patients with moderately to severely active ulcerative colitis who had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent. The study showed that Jyseleca 200mg was well-tolerated and efficacious as induction and maintenance therapy with no new safety findings reported. Jyseleca was approved in Japan in September 2020 for the treatment of rheumatoid arthritis (RA), including the prevention of structural joint damage, in patients who had inadequate response to conventional therapies.

Gilead Japan will hold the marketing authorization of Jyseleca in Japan and will be responsible for product supply. Eisai will be responsible for product distribution, and together with EA Pharma, its subsidiary focused on gastrointestinal diseases, will jointly commercialize the medicine to make it available to physicians and patients across the country.

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, Great Britain and Japan 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 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. The interview form from the Japanese Ministry of Health, Labour and Welfare is available at 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.glpag.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. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. When used in this press release, the words "ongoing," "may," "who," "will," "plan" and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to: statements regarding the global R&D collaboration with Gilead and product supply of filgotinib in moderate-to-severe UC in Japan; statements regarding product distribution by Eisai of filgotinib in moderate-to-severe UC in Japan; statements regarding joint commercialization in Japan of filgotinib in moderate-to-severe UC by Eisai and its subsidiary EA Pharma; and other statements and expectations regarding commercial sales for filgotinib and rollout in Europe. These risks, uncertainties and other factors include, without limitation, risks related to continued regulatory review of filgotinib following approval by relevant regulatory authorities, including the EMA's planned safety review of JAK inhibitors used to treat certain inflammatory disorders, and the risk that the EMA's planned safety review may negatively impact acceptance of filgotinib more widely by patients, the medical community, and healthcare payors, as well as the risk that the MHLW could undertake a similar review; the risk that regulatory authorities may require additional post-approval trials of filgotinib or any other product candidates that are approved in the future; risks related to Galapagos' reliance on third parties, and risks related to the ongoing COVID-19 pandemic. For a discussion of other risks and uncertainties and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (SEC), as supplemented and/or modified by any other filings and reports that we have made or will make with the SEC in the future. All information in this press release is as of the date of the release, and Galapagos undertakes no duty to update this information unless required by law or regulation.