Galapagos initiates Phase 3 program with filgotinib in patients with active axial spondyloarthritis

- OLINGUITO Phase 3 program in adults with axial spondyloarthritis (AxSpA) to include two parallel studies to investigate the efficacy and safety of filgotinib in patients with active radiographic AxSpA (r-AxSpA) and non-radiographic AxSpA (nr-AxSpA)
- Results from Phase 2 TORTUGA study showed that filgotinib 200mg was efficacious and well-tolerated in patients with r-AxSpA
- Filgotinib, an oral, once-daily JAK1 preferential inhibitor, is currently approved in Europe and Japan for the treatment of rheumatoid arthritis (RA) and ulcerative colitis (UC)

Mechelen, Belgium; 26 April 2023, 22:01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) today announced that the first patient was randomized in OLINGUITO, the pivotal Phase 3 program of filgotinib in AxSpA. Topline results are expected in H2 2025.

In the Phase 2 TORTUGA study, filgotinib 200mg achieved significantly greater improvements in Ankylosing Spondylitis Disease Activity Score (ASDAS)[1] at Week 12, the primary endpoint, and had an encouraging safety profile in patients with active r-AxSpA who had not responded to conventional treatment.[2]

“Axial spondyloarthritis is a chronic, painful, highly invalidating inflammatory condition that can profoundly impact patients’ quality of life,” said Prof. Xenofon Baraliakos, Professor of Internal Medicine and Rheumatology at Ruhr-University Bochum, Germany and Coordinating Investigator of the study. “There is a high unmet need for effective oral treatment options for this condition. I am pleased that the first trial sites have been initiated and look forward to continuing to work with Galapagos and with the other study sites to rapidly enroll patients in this pivotal trial.”

“Patients with AxSpA face a significant disease burden and given the limited available therapies, there remains a high unmet medical need for effective oral treatment options,” said Daniele D’Ambrosio, MD, PhD, Therapeutic Area Head, Immunology, at Galapagos. “Filgotinib has demonstrated a consistent efficacy and safety profile across a range of patient populations, and inflammatory conditions and has the potential to address the needs of patients living with AxSpA. We look forward to advancing the OLINGUITO program and to working collaboratively with our clinical partners.”

The OLINGUITO global Phase 3 program (NCT05785611) consists of two randomized, placebo-controlled, double-blind, multi-center, parallel-group studies. The objectives of the studies are to investigate the efficacy and safety of orally administered filgotinib for 16 weeks in 476 patients with active r-AxSpA (Study A) and nr-AxSpA (Study B) who have had an inadequate response to conventional or biological treatment. Each study will enroll approximately 238 patients who are randomized 1:1 to receive filgotinib 200mg or placebo once-daily. The primary endpoint for Study A and Study B is the proportion of patients who achieve an ASAS40[3] response at Week 16 in compliance with the European Medicines Agency’s (EMA) guidelines. The double-blind studies will be followed by an open-label treatment period in which all patients will receive filgotinib 200mg once-daily up to Week 52. Patients from Study A and Study B who achieve sustained low disease activity in the open-label treatment period will be re-randomized 1:1 at Week 52 to receive double-blind filgotinib 100mg or 200mg up to Week 104.

About axial spondyloarthritis

Axial spondyloarthritis (AxSpA), also known as ankylosing spondylitis is a chronic inflammatory disease that involves primarily the sacroiliac joints (SIJs) and the spine, and is characterized by pain, stiffness and fatigue often leading to functional impairment. There are two distinct clinical presentations of AxSpA, radiographic and non-radiographic. In patients with radiographic AxSpA (r-AxSpA), the disease is confirmed by the

[1] The Ankylosing Spondylitis Disease Activity Score (ASDAS) is an index to assess disease activity in Ankylosing Spondylitis (AS).
[2] Van Der Heijde D. Efficacy and safety of filgotinib, a selective Janus kinase 1 inhibitor, in patients with active ankylosing spondylitis (TORTUGA): results from a randomised, placebo-controlled, phase 2 trial *Lancet* 2018;392:2378-87.
[3] Percentage of Participants Achieving SpondyloArthritis International Society 40% improvement.

presence of damage in the SIJ on x-Ray. In non-radiographic AxSpA (nr-AxSpA), this sign is absent, and presence of disease is confirmed by MRI or genetic features (i.e. presence of HLA B27). First symptoms indicative of AxSpA tend to develop in young adults, aged 20 to 30 years. Typical early symptoms of the disease include inflammatory back pain, which is characterized by nocturnal pain and prolonged morning stiffness of the (lower) back with impaired physical function. Many patients present with articular (arthritis, dactylitis) and extra-articular (for example inflammatory bowel disease, uveitis, psoriasis) symptoms associated with AxSpA. Studies report the prevalence of AxSpA ranges from 9 to 30 per 10,000 in the general population, depending on geographic area, study population or data source, case definition, and ascertainment methods.[4]

About filgotinib

Filgotinib is marketed as Jyseleca® in Europe and Japan for the treatment of adults with moderate to severe active RA who have responded inadequately or are intolerant to one or more disease modifying anti-rheumatic drugs. Filgotinib is also marketed as Jyseleca® in Europe and Japan for the treatment of adult patients with moderate to severe active UC who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent. Jyseleca® 100mg and 200mg are registered in the above-mentioned territories. 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, respectively. The interview form from the Japanese Ministry of Health, Labour and Welfare is available at www.info.pmda.go.jp.

Jyseleca® is a trademark of Galapagos NV and Gilead Sciences, Inc. or its related companies. Except for filgotinib's approval as Jyseleca® for the treatment of moderate to severe active RA and UC by the relevant regulatory authorities in the European Union, Great Britain, and Japan, our drug candidates are investigational; their efficacy and safety have not been fully evaluated by any regulatory authority.

About Galapagos

Galapagos is a fully integrated biotechnology company focused on discovering, developing, and commercializing innovative medicines. We are committed to improving patients' lives worldwide by targeting diseases with high unmet needs. Our R&D capabilities cover multiple drug modalities, including small molecules and cell therapies. Our portfolio comprises discovery through to commercialized programs in immunology, oncology, and other indications. Our first medicine for rheumatoid arthritis and ulcerative colitis is available in Europe and Japan. For additional information, please visit www.glpg.com or follow us on LinkedIn or Twitter.

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Forward Looking Statements

This press release includes forward-looking statements, all of which involve certain risks and uncertainties. These statements are often, but not always, made through the use of words or phrases such as "will," "can," "commit," "potential," "remains," "continue," "rapid," "unmet," "advance," "encouraging," "working," "consists," "achieve," and "improve," as well as similar expressions. Forward-looking statements

[4] Wang R, Ward MM. Epidemiology of axial spondyloarthritis: an update. *Curr Opin Rheumatol*. 2018 Mar;30(2):137-143.

contained in this release include, but are not limited to, statements related to our plans and strategy with respect to filgotinib, including our planned Phase 3 clinical trial in AxSpA, r-AxSpA and nr-AxSpA with filgotinib, and the OLINGUITO or TORTUGA study, statements in relation to the envisaged timelines for the OLINGUITO study, and statements regarding the timing with respect to the OLINGUITO study. Any forward-looking statements in this release are based on our management's current expectations and beliefs and are not guarantees of future performance. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause our actual results, performance or achievements to be materially different from any historic or future results, performance or achievements expressed or implied by such statements. These risks, uncertainties and other factors include, without limitation, the risk that the clinical study with filgotinib for AxSpA, r-AxSpA and nr-AxSpA, OLINGUITO, and any future clinical studies with filgotinib may not be completed in the currently envisaged timelines or at all, the inherent risks and uncertainties associated with competitive developments, clinical trial and product development activities, including with respect to the OLINGUITO study, risks related to regulatory approval requirements (including that data from the ongoing and planned clinical research programs may not support the registration of filgotinib for indications in AxSpA, r-AxSpA and/or nr-AxSpA due to safety, efficacy or other reasons), risks related to our reliance on collaborations with third parties, the risk that our estimations regarding our filgotinib development program and regarding the commercial potential of filgotinib may be incorrect, the risk that we will not be able to continue to execute on our currently contemplated business plan and/or will need to revise our business plan, and risks related to the COVID-19 pandemic, as well as those risks and uncertainties identified 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. Given these risks and uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. In addition, even if our results, performance or achievements are consistent with such forward-looking statements, they may not be predictive of results, performance or achievements in future periods. These forward-looking statements speak only as of the date of publication of this release. We expressly disclaim any obligation to update any such statements in this release unless required by law or regulation.