Galapagos announces CHMP adoption of PRAC's recommendation for Jyseleca® following extensive safety review of all JAK inhibitors

- Supportive outcome for Jyseleca as treatment option with a positive benefit/risk profile after review of safety data of all JAK inhibitors approved in Europe for treatment of inflammatory conditions
- This follows the recommended harmonization of EU labels for all JAK inhibitors by Pharmacovigilance Risk Assessment Committee (PRAC)
- For patients aged ≥65 years, current or long-time past smokers and patients with a history of atherosclerotic cardiovascular (CV) disease or other CV and malignancy risk factors, risk minimization measures have been adopted

Mechelen, Belgium; 11 November 2022, 13.15 CET; Galapagos NV (Euronext & NASDAQ: GLPG) today announced that the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), has adopted PRAC's recommendation to add measures to minimise the risk of serious side effects with JAK inhibitors for chronic inflammatory disorders.

"JAK inhibitors are an important treatment option for patients based on individual benefit/risk and we see this outcome as a positive evolution in supporting the best use of the JAK inhibitor class" said Dr. Walid Abi-Saab, Chief Medical Officer of Galapagos. "Jyseleca is the only 2nd generation JAK inhibitor with JAK1 preferential inhibition of both approved doses, as well as the possibility of treating with the lowest effective dose in both RA and UC. We are very pleased with today's outcome as we continue our mission to improve lives of people living with inflammatory diseases."

The product labels of all JAK inhibitors will be updated to include a precautionary approach for patients aged 65 years or above, those at increased risk of major cardiovascular problems (such as heart attack or stroke), those who smoke or have done so for a long time in the past and those at increased risk of cancer. For those at-risk patients, the recommendation is that JAK inhibitors, including Jyseleca, should be used only if no suitable treatment alternatives are available. The CHMP followed PRAC's recommendation that JAK inhibitors should be used with caution in patients with risk factors for blood clots in the lungs and in deep veins (venous thromboembolism, VTE) other than those listed above.

Following today's CHMP opinion, filgotinib 200mg once daily remains the recommended dose for the treatment of patients with RA. For patients with UC, filgotinib 200mg once daily remains the recommended dose for induction and maintenance therapy. Dose adjustments are recommended for patients aged 65 years or above and/or at risk of major adverse cardiac events (MACE), VTE or malignancy, namely 100mg once daily dose in patients with RA, which can be escalated to 200mg in case of insufficient disease control. For at-risk patients with UC, the initiation dose remains unchanged, but a maintenance dose of 100mg should be considered. In case of a flare of disease, the dose should be escalated to 200mg once daily. For long-term treatment in patients with above risk factors, the lowest effective dose should be used.

"The recommendation by the PRAC reflects the concerns raised by the substance class mainly in older patients with rheumatoid arthritis," said Dr. Stefan Schreiber, Professor of Medicine and Gastroenterology at the Christian-Albrechts-University in Kiel, Director of the Clinic for Internal Medicine at the University Hospital Schleswig-Holstein and Leader of Translational Inflammation Research Group in the Kiel University. "It is comforting to see that we still have the option for a benefit-oriented use of filgotinib in ulcerative colitis to provide fast anti-inflammatory efficacy to the main patient group."

Professor Lars Erik Vølund Kristensen, Professor and CSO at the Parker Institute, University of Copenhagen and Associate Professor at Lund University, Sweden, said, "It is reassuring to see that we can still use JAK inhibitors to help a large proportion of our arthritis patients to obtain fast acting and effective anti-inflammatory treatment. I find that PRAC's recommendation harmonizes well with the concerns raised by the Oral Surveillance study, which included older rheumatoid arthritis patients with cardiovascular risk factors."

The CHMP opinion follows the recommendation of the PRAC which carried out a safety review (Article 20 procedure) of all EU-approved JAK inhibitors, including filgotinib, following the Oral Surveillance data on tofacitinib and recent data from a retrospective observational study with baricitinib. The Article 20 procedure is a specific pharmacovigilance (PV) procedure which allowed the EMA to investigate the quality, efficacy, and safety issues for one or more centrally approved products – in this case a safety review on MACE, VTE, serious infections, malignancies, and mortality for the JAK inhibitors authorised in inflammatory diseases.

The European Commission decision is expected by January 2023, approximately 60 days after today's CHMP opinion, following which the language in the 'special warnings and precautions for use' and the 'posology' sections of the Summary of Product Characteristics (SmPC) will be updated.

About filgotinib
Filgotinib is marketed as Jyseleca in the European Union (incl. Norway), 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 is also marketed as Jyseleca in the European Union (incl. Norway), Great Britain, and Japan 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. Jyseleca (filgotinib) 100mg and 200mg are registered in the above-mentioned territories. 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.

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 moderately to severely 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 Rheumatoid Arthritis
Rheumatoid arthritis (RA) is an autoimmune inflammatory disease that primarily causes pain, stiffness and swelling in the joints. RA often follows a painful, progressively debilitating course, depriving patients of the ability to continue their daily lives and leading to physical disability. Despite current treatments, RA continues to pose a substantial burden to people living with the disease, comprised of the daily health issues directly related to their RA, such as pain, and the complications of managing comorbid conditions.[1,2,3]

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 2.5 - 3 million people[4] are affected by IBD, which includes UC and Crohn's disease (CD). UC is a chronic inflammatory condition characterized by periods of flare ups followed by remission. In addition to the physical impact from flare ups, there is also a 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.

[1] Taylor PC, Moore A, Vasilescu R, Alvir J, Tarallo M. A structured literature review of the burden of illness and unmet needs in patients with rheumatoid arthritis: a current perspective. Rheumatology International. 2016;36(5):685-95.
[2] Radner H, et al. Comorbidity affects all domains of physical function and quality of life in patients with rheumatoid arthritis Rheumatology 2011 Feb;50(2):381-8.
[3] An J, et al. Prevalence of comorbidities and their associations with health-related quality of life and healthcare expenditures in patients with rheumatoid arthritis Clin Rheumatol. 2019; 38(10):2717-2726.
[4] Burisch J. et al. Journal of Crohn's and Colitis (2013); 7:322-337.

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 Phase 4 programs in immunology, oncology and other indications. Our first medicine for rheumatoid arthritis and ulcerative colitis is available in the European Union, Norway, Great Britain, 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 are not always, made through the use of words or phrases such as "possibility," "will," "continue," "expect," "should," and "recommendation," as well as similar expressions. Forward-looking statements contained in this release include, but are not limited to, statements regarding the PRAC recommendation for filgotinib, statements regarding the expected timing of the EC's decision, statements related to Galapagos' plans and strategy with respect to Jyseleca, statements relating to interactions with regulatory authorities, the timing or likelihood of additional regulatory authorities' approval of marketing authorization for filgotinib for RA, UC or any other indication for filgotinib in Europe, Great Britain, or Japan. Any forward-looking statements in this release are based on Galapagos 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 Galapagos' actual results, performance or achievements to be materially different from any historic or future results, performance or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and other factors include, without limitation, the risk that ongoing and future clinical studies with filgotinib may not be completed in the currently envisaged timelines or at all, the inherent risks associated with clinical trial and product development activities, including the filgotinib clinical program and the FILOSOPHY and FINCH 4 LTE study, the inherent risks and uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from the ongoing and planned clinical research programs, including but not limited to the data from the ongoing FILOSOPHY or FINCH 4 LTE study, may not support registration or further development of filgotinib due to safety, efficacy or other reasons), the risks related to continued regulatory review of filgotinib following approval by relevant regulatory authorities, including EMA's safety review of JAK inhibitors used to treat certain inflammatory disorders, the risks that regulatory authorities may require additional post-approval trials of filgotinib or any other product candidates that are approved in the future, Galapagos' reliance on collaborations with third parties (including our collaboration partner for filgotinib, Gilead) and that Galapagos' estimations regarding its filgotinib development program and regarding the commercial potential of filgotinib may be incorrect, 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, and risks related to the ongoing 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 Galapagos' 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. Galapagos expressly disclaims any obligation to update any such forward-looking statements in this release unless required by law or regulation.