Galapagos announces completion of patient enrollment for DIVERSITY Phase 3 study with filgotinib in Crohn's Disease

- **1,374 patients enrolled into the phase 3 study across 369 global sites**
- **Topline data anticipated in H1 2023**
- **Galapagos will assume responsibility for the DIVERSITY study**

Mechelen, Belgium; 4 October 2021, 07.01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) today announced randomization of the last patient into the multi-center, global DIVERSITY Phase 3 study. The study is designed to evaluate the efficacy and safety of filgotinib, a JAK1 preferential inhibitor, in the induction and maintenance of remission in patients with Crohn's Disease (CD).

The DIVERSITY study enrolled 1,374 participants with moderately to severely active CD, including biologic-naïve and biologic-experienced patients. The study evaluates the safety and efficacy of 100mg and 200mg filgotinib versus placebo on clinical remission and endoscopic response, in a 10-week induction phase, followed by a 47-week maintenance phase. Topline results of the DIVERSITY study are anticipated in H1 2023.

Dr. Walid Abi-Saab, Chief Medical Officer, Galapagos NV said: "This is an important milestone in the DIVERSITY program, as it brings us closer to delivering robust evidence to assess the use of our JAK1 preferential inhibitor as a potentially new class of medicine in the treatment of patients with Crohn's Disease. I would like to thank the patients and the clinical trial centers for participating in this important program, especially during the recent COVID-19 pandemic, which has been a particularly challenging time for the health services and society as a whole."

The DIVERSITY clinical program design was informed by results from the Phase 2 FITZROY study, with filgotinib, which provided positive results for the use of this JAK1 inhibitor in patients with active CD. Full results were reported in *The Lancet*.[1]

The use of filgotinib for CD is investigational and is not approved anywhere globally.

Galapagos will assume operational and financial responsibility for DIVERSITY
In agreement with Gilead, Galapagos will assume sponsorship of and operational and financial responsibility for the ongoing DIVERSITY clinical study, evaluating filgotinib in CD, and its long-term extension study. The parties intend to complete the transfer no later than June 30, 2022. Under the terms of the agreement and upon completion of the transfer, Gilead will make a one-time payment of $15 million to Galapagos in consideration for Galapagos assuming responsibility for the DIVERSITY clinical study. From April 1, 2022, Galapagos will also be solely responsible for all development costs for the DIVERSITY clinical study. In addition, if the European Medicines Agency grants regulatory approval of filgotinib for the treatment of CD based on data from the DIVERSITY trial, then royalties payable by Galapagos to Gilead will be reduced by 30% across all filgotinib indications and will become 5.6 to 10.5% of net sales in Europe. These royalties are payable as of 2024. Gilead remains responsible for commercial activities outside of Europe.

About Crohn's Disease
Crohn's disease is a type of inflammatory bowel disease in which the well-controlled balance of the intestinal immune system is disturbed. CD causes ulcerations that may affect any part of the digestive system from mouth to anus. The cause of the disease is unknown, with onset usually between the ages of 15 and 35. Patients suffer from abdominal pain, diarrhea (often blood), vomiting, fever and weight loss. Estimates suggest there could be up to 1.6 million people living with CD across Europe and up to 78,000 new cases every year.[2]

About the DIVERSITY Phase 3 Study
DIVERSITY consists of a combined, double-blind, placebo-controlled Phase 3 study, enrolling 1,374 patients from 369 centers worldwide. The study compares the efficacy of filgotinib 100mg or 200mg once-daily oral treatment versus placebo in the induction and maintenance of clinical remission measured by Crohn's Disease Activity Index (CDAI) score and endoscopic response measured as simple endoscopic score for Crohn's Disease (SES-CD) at week 10 and week 58, in biologically-naive and biologically-experienced patients with moderately to severely active CD. There are EU-specific co-primary objectives that evaluate clinical remission measured by Patient Reported Outcome (PR02) and endoscopic response (SES-CD) at Week-10 and Week-58. In addition to clinical endpoints the study will also evaluate the effects on Health-Related Quality of Life (HRQoL) scores and Health Care Resource Utilization (HCRU) at Week-10 and Week-58. Safety will be evaluated by assessment of clinical laboratory tests, physical examination, vital signs measurements at various timepoints during the study, and by the documentation of Adverse Events.

For DIVERSITY study information visit: ClinicalTrials.gov Identifier NCT02048618

About the filgotinib collaboration
Gilead and Galapagos NV are partners in a global collaboration to develop and commercialize filgotinib, which is approved and marketed as Jyseleca® 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). Galapagos will be responsible for the commercialization of filgotinib in Europe (transition from Gilead to Galapagos 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. Applications to extend the approved indication of filgotinib to include ulcerative colitis have been filed in the European Union, 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.

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.

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.

Contact
Investors:
Elizabeth Goodwin
VP Investor Relations
+1 781 460 1784

Sofie Van Gijsel
Senior Director Investor Relations
+1 781 296 1143

Sandra Cauwenberghs
Director Investor Relations
+32 495 58 46 63
ir@glpg.com

Media:
Anna Gibbins
Senior Director Therapeutic Areas Communications
+44 7717 801900

Evelyn Fox
Director Executive Communications
+31 65 3591 999
communications@glpg.com

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, including the DIVERSITY study and filgotinib clinical program, the timeline of topline results from clinical trials, competitive developments, and regulatory approval requirements, including the risk that the results of the DIVERSITY study may not support continued approval of filgotinib or may not support registration or further development in CD or other indications due to safety or efficacy concerns 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, 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, the risk that the parties would not be able to complete the contemplated transfer of the DIVERSITY STUDY in a timely manner or at all, the risk that parties may not be able to successfully implement transfer of rights and activities in a timely or efficient manner or at all, Galapagos' reliance on collaborations with third parties, including the collaboration with Gilead for filgotinib, the risk that Galapagos' estimations regarding its filgotinib development program may be incorrect and the uncertainty regarding estimates of the commercial potential of filgotinib, the risks and costs involved in selling and marketing filgotinib, the timing of and risks related to the implementation of the transition of the European commercialization responsibility of filgotinib from Gilead to us, including the risk that the transition will not be completed on the currently contemplated timeline or at all, and the risk that the transition will not have the currently expected results for our business and results of operations; and the uncertainties relating to the impact of the COVID-19 pandemic on our strategy, business plans and focus, 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.

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[1] *The Lancet* Vol. 389 No. 10066 p266–275 Published: December 14, 2016
[2] *Journal of Crohn's and Colitis*, Volume 7, Issue 4, May 2013, Pages 322 337, https://doi.org/10.1016/j.crohns.2013.01.010
[3] https://www.crohnscolitisfoundation.org/sites/default/files/2019-02/Updated%20IBD%20Factbook.pdf (last accessed 01.09.21)