The Lancet publishes FITZROY study results with filgotinib in Crohn’s disease

Mechelen, Belgium; 12 December 2016 – Galapagos NV (Euronext & NASDAQ: GLPG) reports publication of the Phase 2 study with filgotinib in Crohn’s disease in The Lancet.

"Filgotinib, a selective JAK1 inhibitor, induces clinical remission in patients with moderate-to-severe Crohn’s disease: results from the phase II double-blind, randomized, placebo-controlled FITZROY study,” by Dr Severine Vermeire et al. describes the study design and full results and can be found online at www.glpg.com/filgotinib.

"Filgotinib could represent the first new oral treatment for CD in many years, and Phase 3 trials with the compound are underway,” said Dr Vermeire. “FITZROY was the first double-blind, placebo-controlled study to use centrally read endoscopies to ensure the selective recruitment of patients with active disease including mucosal ulceration.”

The Lancet also publishes an editorial that highlights the Fitzroy study and results: “There are several strengths in this well-designed trial. The use of a number of clinical, endoscopic, and biochemical endpoints ensures robustness of benefit of treatment and provides strong support for further investigation of this therapeutic mechanism. The requirement of endoscopically active disease at randomization and use of central readers to adjudicate eligibility and efficacy increased the clarity in the efficacy signal and reduced the potential of bias,” said Dr Ashwin Ananthakrishnan in this editorial commentary in the same issue of The Lancet.

Galapagos and Gilead entered into a global collaboration for the development and commercialization of filgotinib in inflammatory indications. Gilead initiated the FINCH Phase 3 study in rheumatoid arthritis in August, the DIVERSITY Phase 3 study in CD in November and the SELECTION Phase 2b/3 program in ulcerative colitis earlier this month.

Filgotinib is an investigational drug and its efficacy and safety have not been established.

About the FITZROY study and results
The FITZROY Phase 2 study (174 patients) evaluated filgotinib once-daily versus placebo in patients with moderately to severely active Crohn’s disease and mucosal ulceration. Patients recruited were either anti-TNF naïve or anti-TNF failures. The study comprised two parts, each of 10 weeks duration: the first part investigated the safety and efficacy of filgotinib 200 mg once daily versus placebo, while the second part of the study investigated continued treatment through 20 weeks in an observational exploratory design. The FITZROY study achieved the primary endpoint of clinical remission at 10 weeks: the percentage of patients achieving a Crohn’s Disease Activity Index (CDAI) score below 150 was significantly higher in patients treated with filgotinib versus patients receiving placebo. Improvement in quality of life, histopathology, endoscopy assessment and biomarkers of inflammatory activity were also observed at Week 10. Clinical responses were maintained from week 10 to week 20. Non-responders in the placebo arm from the first 10 weeks received filgotinib 100 mg in the second 10 weeks and showed improvement in clinical remission during the second part of the study.

Overall, in the FITZROY study at 20 weeks of treatment, filgotinib demonstrated a favorable safety profile consistent with the previous DARWIN studies in RA. An increase in hemoglobin was also
observed in FITZROY, without difference between filgotinib and placebo. No clinically significant changes from baseline in neutrophils or liver function tests were observed.

For information about the studies with filgotinib in IBD: www.clinicaltrials.gov
For more information about filgotinib: www.glpg.com/filgotinib

About Galapagos
Galapagos (Euronext & NASDAQ: GLPG) is a clinical-stage biotechnology company specialized in the discovery and development of small molecule medicines with novel modes of action. Our pipeline comprises a pipeline of Phase 3, Phase 2, Phase 1, pre-clinical, and discovery programs in cystic fibrosis, inflammation, fibrosis, osteoarthritis and other indications. We have discovered and developed filgotinib: in collaboration with Gilead we aim to bring this JAK1-selective inhibitor for inflammatory indications to patients all over the world. Galapagos is focused on the development and commercialization of novel medicines that will improve people’s lives. The Galapagos group, including fee-for-service subsidiary Fidelta, has approximately 480 employees, operating from its Mechelen, Belgium headquarters and facilities in The Netherlands, France, and Croatia. More information at www.glpg.com.

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Forward-looking statements
This release may contain forward-looking statements, including statements regarding the potential activity of filgotinib, the anticipated timing of clinical studies with filgotinib, and the progression and results of such studies. Galapagos cautions the reader that forward-looking statements are not guarantees of future performance. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition and liquidity, performance or achievements of Galapagos, or industry results, to be materially different from any historic or future results, financial conditions and liquidity, performance or achievements expressed or implied by such forward-looking statements. In addition, even if Galapagos’ results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. Among the factors that may result in differences are the inherent 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 in rheumatoid arthritis, Crohn’s disease and/or ulcerative colitis may not support registration or further development of filgotinib due to safety, efficacy or other reasons), Galapagos’ reliance on collaborations with third parties (including its collaboration partner for filgotinib, Gilead), and estimating the commercial potential of Galapagos’ product candidates. A further list and description of these risks, uncertainties and other risks can be found in Galapagos’ Securities and Exchange Commission (SEC) filings and reports, including in Galapagos’ most recent annual report on form 20-F filed with the SEC and subsequent filings and reports filed by Galapagos with the SEC. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. Galapagos expressly disclaims any obligation to update any such forward-looking statements in this document to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements, unless specifically required by law or regulation.