

Press release

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New Phase 2 studies with filgotinib in small bowel and fistulizing Crohn's disease

Mechelen, Belgium; 10 March 2017 – Galapagos NV (Euronext & NASDAQ: GLPG) announces two new Phase 2 studies investigating filgotinib in small bowel Crohn's disease as well as in fistulizing Crohn's disease. These studies are being led by filgotinib collaboration partner Gilead Sciences, Inc.

The first additional Crohn's disease Phase 2 study is a multi-center, randomized, double-blind, placebo-controlled study to assess the safety and efficacy of the investigational selective JAK1 inhibitor filgotinib in adult patients with small bowel Crohn's disease. Approximately 100 patients in North America and Europe are planned to be randomized in the study to receive one of two doses of filgotinib or placebo, administered for 24 weeks. The primary objective will be to compare filgotinib to placebo in establishing clinical remission, defined as CDAI<150, in patients with small bowel Crohn's disease at week 24.

The second Phase 2 study is a multi-center, randomized, double-blind, placebo-controlled study to assess the safety and efficacy of the selective JAK1 inhibitor filgotinib in adult patients with perianal fistulizing Crohn's disease. Approximately 75 patients are planned to be randomized in the study to receive one of two doses of filgotinib or placebo administered for 24 weeks. The primary objective is to evaluate the efficacy of filgotinib, compared to placebo, in establishing a combined fistula response at week 24.

Eligible patients who complete either study may be able to continue in a long term extension study.

These new Phase 2 studies with filgotinib follow the initiation of the DIVERSITY Phase 3 study in Crohn's disease. Gilead further initiated the FINCH Phase 3 program in rheumatoid arthritis and the SELECTION Phase 2b/3 study in ulcerative colitis in 2016.

Filgotinib is an investigational drug and its efficacy and safety have not been established. For information about the studies with filgotinib: <u>www.clinicaltrials.gov</u> For more information about filgotinib: <u>www.glpg.com/filgotinib</u>

About small bowel Crohn's disease (SBCD)

Crohn's disease causes chronic inflammation and erosion of the intestines. It can affect different regions of GI tract including the stomach and small and large intestines. While isolated SBCD is an uncommon presentation of CD, involvement of some portion of the small bowel (SB), particularly the ileum, is common. Precise estimates of SB involvement vary in the literature, but generally, some involvement occurs in up to 70% of patients, with isolated SB disease reported in up to a third of patients {Hall 2015}. Patients with SBCD experience cramps, diarrhea, abdominal discomfort (sometimes severe) and fistulae.¹ While there is no therapy approved for SBCD specifically, current treatment involves anti-tumor necrosis factor antibodies and other biologics.

About perianal fistulizing Crohn's disease

Fistulae are inflammatory tracts that most often occur between the distal colon and the perianal region. Fistulae are one of the most severe sequelae of luminal CD and the lifetime risk of occurrence is close to 50% of those with active CD. Fistulizing CD may also cause painful abscesses in the

¹ From http://www.healthline.com/health/crohns-disease/types#TheFiveTypes2



abdomen. In acute fistulizing perianal CD, the lesions represent manifestations of severe disease activity and are concomitantly managed with medications that treat underlying luminal disease (e.g., anti-TNF antibodies). Fistulae may progress to destruction of the sphincter apparatus necessitating proctectomy after years of continual inflammation and tissue erosion. Despite use of available therapies, long term or durable remission rates for fistulizing CD are still low at approximately 20%.

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 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 510 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 Galapagos' strategic ambitions, 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 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 forwardlooking 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.