

Filgotinib meets primary endpoint in phase 2 study in patients with moderate to severe Crohn's disease

- **First JAK-inhibitor to show efficacy in Crohn's disease**
- **48% clinical remission rate, statistically significant versus placebo after 10 weeks induction therapy**
- **Significant improvements in clinical response and IBDQ quality of life**
- **Filgotinib safety profile similar to that previously observed**

Webcast presentation of the results to be held tomorrow 8 December, 16.00 CET/10 AM EDT/7 AM PDT, +1646 254 3373 access code 4725658 more call number info further down

Mechelen, Belgium; 7 December 2015 – Galapagos NV (Euronext & NASDAQ: GLPG) announced today that 200 mg filgotinib is shown to be effective and safe as once-daily, oral induction treatment in moderate to severe Crohn's disease, based on the FITZROY phase 2 study at the 10-week interim analysis. The study achieved the primary endpoint of clinical remission: the percentage of patients achieving a CDAI score lower than 150 was significantly higher in patients treated with filgotinib versus patients receiving placebo. Filgotinib was shown to be well tolerated in the FITZROY study, strengthening its favorable safety profile.

175 patients with moderate to severe Crohn's disease were enrolled in FITZROY, a double-blind, placebo-controlled study. Patients recruited were either anti-TNF naïve or anti-TNF failures. The full study has two parts of 10 weeks each: the first part – reported today - investigates the effect of filgotinib 200mg once daily versus placebo as induction therapy. As the study is still ongoing, individual data remain blinded. Galapagos expects to report the full 20 week results for FITZROY in the first half of 2016.

Summary of clinical key endpoints after interim analysis at 10 weeks:

	placebo n=44	filgotinib 200mg n=128	p-value
Clinical remission (CDAI lower than 150) (%), ITT-NRI	23	48	0.0067
Clinical response, (CDAI decrease 100 points or more) (%), ITT-NRI	41	60	0.0386
Total IBDQ score, mean change from baseline, ITT-LOCF	17.56	33.82	0.0045

Overall, in the FITZROY study, filgotinib demonstrated a favorable safety profile consistent with the previous DARWIN studies. Similar incidences in SAEs and AEs were observed between filgotinib and placebo, with the majority of the SAEs related to worsening of Crohn's disease. In the FITZROY study, filgotinib showed a favorable lipid profile with an increase in HDL and no change in LDL, resulting in an improved atherogenic index. 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 in this study.

“These data are robust and important because collectively they show that patients who received filgotinib had higher rates of clinical remission and their quality of life improved considerably. This was further accompanied by a significant proportion of patients normalizing their CRP, an objective biomarker of inflammation,” commented principal investigator Dr Séverine Vermeire, Department of Gastroenterology, University hospitals Leuven. “It is also important to note that during the first 10 weeks of dosing no unexpected safety findings emerged.”

“The results of this study are exciting and show that with an oral treatment and new mechanism of action we are able to induce a high rate of clinical remission in moderate to severe Crohn’s disease patients. Taken together with a favorable safety profile, filgotinib has a good potential as future treatment for IBD,” added Dr William Sandborn, Chief, Division of Gastroenterology, University of California San Diego School of Medicine.

“Filgotinib is the first JAK inhibitor to show efficacy in Crohn’s disease, a disease with still few treatment options today,” said Piet Wigerinck, CSO of Galapagos. “These favorable FITZROY study results complement the excellent DARWIN data in rheumatoid arthritis and open up new opportunities in a broader range of inflammatory diseases for filgotinib, our selective JAK-1 inhibitor.”

“We are proud to bring innovative treatments to patients where high unmet medical need exists. We intend to move this drug to Phase 3 as soon as possible,” said Onno van de Stolpe, CEO of Galapagos. “Once again, Galapagos has demonstrated that its technology platform has the potential to deliver safe and efficacious drugs which actually can modify the disease for patients. Our pipeline is filling with later stage programs based on the same approach we used to discover and develop filgotinib.”

Conference call and webcast presentation

Galapagos will conduct a conference call open to the public tomorrow, 8 December 2015, at 16:00 CET/10 AM EDT/8 AM PDT, which will also be webcasted. To participate in the conference call, please call one of the following numbers ten minutes prior to commencement:

Confirmation Code:	4725658
United Kingdom:	+44(0)20 3427 1928
France:	+33(0)1 76 77 22 40
Toll free France:	0805 636 390
Belgium:	+32(0)2 400 1974
Toll free Belgium:	0800 39271
United States of America:	+1646 254 3373
Netherlands:	+31(0)20 721 9157
Toll free Netherlands:	8000 222 330
Toll free United Kingdom:	0800 279 4849
Toll free phone United States of America:	1855 217 7942

A question and answer session will follow the presentation of the results. Go to www.glpq.com to access the live audio webcast. The archived webcast, PDF of the slides, and a transcript will also be available on the Galapagos website later in the day.

About the study endpoints: CDAI, IBDQ

The Crohn's Disease Activity Index (CDAI) incorporates disease activity indicators in the form of a patient diary. The composite CDAI score is calculated based on 8 elements with various weightings: number of liquid or soft stools each day for 7 days, abdominal pain each day for 7 days, general well-being for 7 days, presence of complications, taking diphenoxylate/atropine, loperamide, or opiates for diarrhea, presence of an abdominal mass, hematocrit of lower than 0.47 in men and lower than 0.42 in women, and percentage deviation from standard weight. Clinical remission is defined as CDAI score lower than 150, while clinical response involves a decrease in CDAI of 100 points or more. Disease states are defined as mild: 150 to 220, moderate to severe: 220 to 450, and severe: more than 450 (adapted from [AGA Perspectives](#), Vol. 9 No. 2, April/May 2013).

The Inflammatory Bowel Disease Questionnaire (IBDQ) is a questionnaire for health-related quality of life assessment in patients with inflammatory bowel diseases: ulcerative colitis and Crohn's disease. It consists of 32 questions divided into four groups: bowel symptoms (10 items), systemic symptoms (5 items), emotional function (12 items) and social function (5 items). Every question has graded responses from 1 to 7, and thus the total score is ranging from 32 to 224 with higher scores representing better quality of life. The IBDQ is a validated assessment tool that reflects important changes in the quality of life of patients with IBD (adapted from Pallis et al, [Inflamm Bowel Dis](#), Volume 10, Number 3, May 2004).

About filgotinib

Filgotinib is a highly selective JAK1 inhibitor discovered and developed by Galapagos using its target and drug discovery technology platform. In more than 700 patient years of rheumatoid arthritis (RA) clinical study experience, filgotinib has shown a rapid onset of action, potentially best-in-class efficacy and to be safe and well tolerated in these studies. The Company is preparing to initiate a Phase 3 program with filgotinib in rheumatoid arthritis in the first half of 2016. Filgotinib is fully proprietary to Galapagos.

About Crohn's disease

Crohn's disease (CD) is an inflammatory bowel disease causing chronic inflammation of the gastrointestinal, or GI, tract with a relapsing and remitting course. The prevalence estimates for CD in North America range from 44 cases to 201 cases per 100,000 persons and in Europe, from 37.5 cases to 238 cases per 100,000 persons. The disease is slightly more common in women, with a peak incidence at the age of 20 to 40 years. The disease is characterized by inflammation that may affect any part of the GI tract from mouth to anus, but most commonly the distal small intestine and proximal colon, causing a wide variety of symptoms including anemia, abdominal pain, diarrhea, vomiting, and weight loss. The characteristic inflammatory response of CD is focal transmural inflammation, frequently associated with granuloma formation, which may evolve to progressive damage over time. Treatment of CD will depend on severity of the disease. The main goal of treatment is to stop the inflammation in the intestine, prevent flare-ups and keep patients' disease in remission. While mild symptoms may respond to an antidiarrheal medicine, antibiotics, and other medicines to control inflammation, severe symptoms are often treated with anti-TNF agents. Anti-TNF agents, however, do not work for all patients, and, in patients who do find therapeutic benefit, they can lose their effect over time as a result of relapse. Anti-TNF agents have also demonstrated side effects arising from long term suppression of the immune system

including increased rate of infections. Unlike in RA, few biologics have been approved in CD and, as such, caregivers have a more limited number of available treatments. The market for CD therapies, across the 10 main healthcare markets, was approximately \$3.2 billion in 2012 and is estimated to exceed \$4.1 billion in 2022, according to a January 2014 GlobalData PharmaPoint report, driven primarily by use of anti-TNF agents.

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 three phase 2, three phase 1, five pre-clinical and 20 discovery studies in cystic fibrosis, inflammation, fibrosis, osteoarthritis and other indications. We are 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 400 employees, operating from its Mechelen, Belgium headquarters and facilities in The Netherlands, France, and Croatia. More information at www.glpq.com.

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Galapagos forward-looking statements

This release may contain forward-looking statements, including, among other things, statements regarding the mechanism of action and profile, and timing of clinical trials and results, of filgotinib. Galapagos cautions the reader that forward-looking statements are not guarantees of future performance. In particular it should be noted that the positive interim results of the FITZROY phase 2 trial with filgotinib in Crohn's disease may not be indicative of future results. 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 that Galapagos' expectations regarding its filgotinib development program may be incorrect, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from Galapagos' ongoing clinical research programs may not support registration or further development of its drug candidates due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties, 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' prospectus filed with the SEC on 14 May 2015 and future 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.