

Regulated information

27 September 2016

# Successful completion of regulatory consultations to progress filgotinib to Phase 3 in inflammatory bowel disease

- Global program to start in Q4'16
- DIVERSITY Phase 3 study in Crohn's disease
- SELECTION Phase 2b/3 study in ulcerative colitis
- 100 mg and 200 mg once daily doses included

Mechelen, Belgium; 27 September 2016, 22.00 CET — Galapagos NV (Euronext & NASDAQ: GLPG) reports the successful completion of discussions with the regulatory authorities in the US and Europe to initiate the DIVERSITY Phase 3 study in Crohn's disease and the SELECTION Phase 2b/3 study in ulcerative colitis with filgotinib. Both studies will investigate efficacy and safety of 100 mg and 200 mg filgotinib oncedaily compared to placebo in patients with moderately to severely active disease including those with prior antibody therapy failure. First dosing is expected in Q4'16.

Both studies will recruit approximately 1,300 patients each from the US, Europe, Latin America, Canada, and Asia/Pacific. The SELECTION Phase 2b/3 study in ulcerative colitis will include a futility analysis, serving as the Phase 2b part of this integrated Phase 2b/3 study. Men and women in both the SELECTION and DIVERSITY studies will be randomized to receive placebo, 100 mg or 200 mg filgotinib. In the US, males may receive 200 mg if they failed at least one anti-TNF and vedolizumab¹. The filgotinib Phase 3 program will also contain a dedicated male patient testicular safety study.

"The outcome of the discussions with US and national European regulatory authorities enables our collaboration partner Gilead to further evaluate filgotinib in IBD," said Dr Piet Wigerinck, Chief Scientific Officer at Galapagos. "The improvements in clinical signs, quality of life, and endoscopy in Crohn's patients reported in the FITZROY Phase 2 study support this next step."

Galapagos and Gilead entered into a global collaboration for the development and commercialization of filgotinib in inflammatory indications. Gilead initiated the FINCH Phase 3 program in rheumatoid arthritis in August 2016.

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

For information about the studies with filgotinib in IBD: <a href="www.clinicaltrials.gov">www.clinicaltrials.gov</a>
For more information about filgotinib: <a href="www.qlpg.com/filgotinib">www.qlpg.com/filgotinib</a>

### **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 maturing 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-

<sup>&</sup>lt;sup>1</sup> Vedolizumab is a monoclonal anti-integrin antibody developed by Millennium Pharmaceuticals.



## Galápagos

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 460 employees, operating from its Mechelen, Belgium headquarters and facilities in The Netherlands, France, and Croatia. More information at <a href="https://www.glpq.com">www.glpq.com</a>.

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This press release contains inside information within the meaning of Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (market abuse regulation).

#### **Forward-Looking Statements**

This release may contain forward-looking statements, including statements regarding any guidance given by Galapagos' management, the anticipated timing of clinical studies with filgotinib, the progression and results of such studies and ongoing interactions with regulatory authorities. 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.