

Press release

18 March 2016, 7.30 CET

# Results from 10-week analysis of Phase 2 study with filgotinib in Crohn's Disease presented at ECCO

Filgotinib is an investigational JAK inhibitor to show clinical efficacy in patients with moderate to severely active Crohn's Disease

Mechelen, Belgium; 18 March 2016: Galapagos (Euronext & NASDAQ: GLPG) announces the presentation of detailed results from the Phase 2 FITZROY study of filgotinib in Crohn's Disease, at the 11<sup>th</sup> Congress of ECCO in Amsterdam, the Netherlands, from March 16 - 19.

Prof Dr Séverine Vermeire, the principal investigator of the FITZROY study, will be presenting the results on the 10-week on treatment analysis. These results from this 174-patient study were reported in December 2015 and indicated that the study achieved the primary endpoint of clinical remission: the percentage of patients achieving a Crohn's Disease Activity Index (CDAI) score lower than 150 was statistically significantly higher in patients treated with filgotinib versus patients receiving placebo (48 percent (61/128) vs. 23 percent (10/44), p<0.05).

The presentation on 18 March, takes place at the Scientific Session in ECCO Fellowship & Grants, at 15.50 – 16.00 hours CET. Filgotinib is the first JAK inhibitor to show clinical efficacy in moderate to severely active Crohn's Disease. Furthermore, filgotinib showed improvement in quality of life (IBDQ) in TNF-naive and TNF-failure populations. The rate of treatment-emergent adverse events was similar between the filgotinib and placebo arms; the most common adverse events occurring in each study arm were infections and infestations (26 percent vs. 23 percent), gastrointestinal disorders (24 percent vs. 23 percent) and nervous system disorders (16 percent vs. 18 percent). The 10-week results support further development of filgotinib in inflammatory bowel disease (IBD). Galapagos and Gilead Sciences also expect to report the full 20-week results for FITZROY in the first half of 2016.

In December 2015, Galapagos and Gilead signed a global collaboration agreement for the global development and commercialization of filgotinib in inflammatory diseases. Under the terms of the agreement, the companies will collaborate jointly on the global development of filgotinib starting with the initiation of Phase 3 trials in rheumatoid arthritis and Crohn's Disease.

## 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 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 440 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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#### Galapagos forward-looking statements

This release may contain forward-looking statements, including statements regarding the promising nature of the results with filgotinib, the potential implications of these results for the future risk-benefit profile of filgotinib and the expected timing of future Phase 3 clinical trials with 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 Phase 2 FITZROY study 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 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 in rheumatoid arthritis and Crohn's disease may not support registration or further development of filgotinib 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) filing and reports, including in Galapagos' prospectus filed with the SEC on 14 May 2015 and subsequent filings and reports filed by the company 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.