

Press release

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# FITZROY Phase 2 study with filgotinib in Crohn's Disease presented as late breaker at DDW 2016

Mechelen, Belgium; 25 May 2016: Galapagos (Euronext & NASDAQ: GLPG) announces the presentation of detailed results from the Phase 2 FITZROY study of filgotinib in Crohn's Disease, at Digestive Disease Week (DDW1) 2016 in San Diego, CA, USA, held from 21-24 May. More information can be found at www.ddw.org.

Prof. Dr. Séverine Vermeire, the principal investigator of the FITZROY study, presented the results from this 174-patient study, initially reported in December 2015. Galapagos reported 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.

The oral presentation, "Filgotinib (GLPG0634), an oral JAK1 selective inhibitor, induces clinical remission in patients with moderate-to-severe Crohn's disease: results from the Phase 2 FITZROY study interim analysis," took place today, during the Clinical science late-breaking abstracts plenary session, abstract #2488299.

In this Phase 2 study, filgotinib also demonstrated improvement in quality of life (IBDQ). The rate of treatment-emergent adverse events was similar between the filgotinib and placebo arms. The results support further development of filgotinib in inflammatory bowel disease (IBD).

The company also presented a poster entitled "The JAK1-selective inhibitor, filgotinib, reverses the disease signature of colon mucosa in experimental colitis." The authors reported filgotinib prevents the changes observed in mucosal gene expression induced by colitis, and that several of these genes also display changes in human IBD. This poster was presented in the session "Cytokines, Signaling and Receptors" on 21 May, abstract #2442351, poster # Sa1844.

As per DDW policy, Galapagos is prohibited from distributing the presentation and poster. Please contact the DDW organization (www.ddw.org) to receive a copy. Galapagos did not provide financial support for the above scientific sessions and did not influence the content in any way. However, research presented within these scientific sessions were supported by Galapagos.

Galapagos and Gilead entered into a global collaboration agreement for the global development and commercialization of filgotinib in inflammatory diseases. The agreement became effective on January 19, 2016. 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 and a Phase 2 trial in ulcerative colitis.

<sup>&</sup>lt;sup>1</sup> The name, logo and acronym of Digestive Disease Week® are the exclusive property of and are trademarked by DDW



## **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 maturing pipeline comprises Phase 2, Phase 1, pre-clinical and 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 <a href="https://www.glpg.com">www.glpg.com</a>.

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#### 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 quarantees 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 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.