Successful completion of End-of-Phase 2 FDA and EMA consultations in rheumatoid arthritis (RA)

- FINCH Phase 3 studies to start in Q3’16
- Three registration studies addressing a broad population of RA patients
- 100 mg and 200 mg once daily dosing in males and females world-wide

Mechelen, Belgium; 24 May 2016 – Galapagos NV (Euronext & NASDAQ: GLPG) reports the successful completion of the discussions with the regulatory authorities in the US and Europe and discloses the doses for the FINCH global Phase 3 program with filgotinib in RA. The FINCH program will investigate efficacy and safety of 100 mg and 200 mg filgotinib once-daily, globally addressing a broad RA patient population, with dosing expected to begin in Q3’16. The FINCH Phase 3 program will also contain a dedicated male patient testicular safety study.

“We are pleased with the outcome of the End-of-Phase 2 discussions with FDA and EMA, as the FINCH program, led by our collaboration partner Gilead, will enable a comprehensive Phase 3 evaluation of simultaneously 100 mg and 200 mg filgotinib in both males and females in major RA patient populations world-wide,” said Piet Wigerinck, Chief Scientific Officer at Galapagos. “Gilead and Galapagos have worked diligently to complete the transition, such that Gilead is now poised to initiate multiple studies with filgotinib in inflammatory diseases.”

Galapagos and Gilead entered into a global collaboration for the development and commercialization of filgotinib for inflammatory indications. In addition to the FINCH program in RA, Gilead expects to initiate a Phase 3 study with filgotinib in Crohn's disease and a Phase 2/3 study in ulcerative colitis in Q3 ’16. Interactions with the regulatory authorities in these indications are still pending and will be reported on later.

For more information about filgotinib: www.glpg.com/filgotinib

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 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 440 employees, operating from its Mechelen, Belgium headquarters and facilities in The Netherlands, France, and Croatia. More information at www.glpg.com.
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 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.