





FINCH filgotinib Phase 3 program initiated in rheumatoid arthritis

- Three studies addressing a broad population of patients with active rheumatoid arthritis
- Filgotinib 100 mg and 200 mg, once daily dosing in males and females worldwide in combination- and as monotherapy

Mechelen, Belgium; 22 August 2016 – Galapagos NV (Euronext & NASDAQ: GLPG) reports the initiation of the FINCH global Phase 3 program investigating the efficacy and safety of 100 mg and 200 mg filgotinib once daily, in rheumatoid arthritis (RA) patient populations, ranging from early stage to biologic-experienced patients.

The **FINCH program** includes three studies with filgotinib. **FINCH 1** is a 52-week, randomized, placebo- and adalimumab-controlled study in combination with methotrexate (MTX) in an expected 1,650 patients who have had inadequate response to MTX. The primary endpoint is ACR20¹ at week 12. The study will also include radiographic assessment at weeks 24 and 52.

FINCH 2 is a 24-week, randomized, placebo-controlled study in an expected 423 patients who are on conventional disease-modifying anti-rheumatic drugs (cDMARD), and have had an inadequate response to biological treatment. The primary endpoint is ACR20 at week 12.

FINCH 3 is a 52-week, randomized study in an expected 1,200 MTX-naïve patients to study filgotinib in combination with MTX, as well as monotherapy. The primary endpoint is ACR20 at week 24. Radiographic progression will also be assessed.

"The FINCH program, led by our collaboration partner Gilead Sciences, Inc., is designed to enable a comprehensive evaluation of 100 mg and 200 mg filgotinib once daily in early stage to biologic-resistant RA patient populations," said Piet Wigerinck, Chief Scientific Officer at Galapagos. "Preparations are well underway to also initiate studies with filgotinib in Crohn's disease and ulcerative colitis in Q4 of this year."

The FINCH program in RA will be conducted in the United States and Europe to start, with other regions to follow. For more information, visit www.clinicaltrials.gov.

Galapagos and Gilead have entered into a global collaboration for the development and commercialization of filgotinib for inflammatory indications. Filgotinib is an investigational agent and its safety and efficacy have not been established. For more information, check www.qlpq.com/filgotinib.

ACR 50 and ACR70 reflect the same, respectively for 50% and 70% response rates.

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¹ American College of Rheumatology 20% (ACR20) response rate signifies a 20% or greater improvement in the number of swollen and tender joints as well as a 20% or greater improvement in three out of five other disease-activity measures.



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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 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 460 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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Forward-Looking Statements

This release may contain forward-looking statements, including statements regarding the anticipated timing of clinical studies with filgotinib. Galapagos cautions the reader that forward-looking statements are not quarantees 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.