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 ACR20 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.glpg.com/filgotinib.

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

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Forward-Looking Statements

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