

Galapagos reports additional data with filgotinib from the Phase 2 FITZROY study

- **Filgotinib: an investigational JAK-inhibitor shows efficacy in Crohn's disease**
- **Clinical responses continued from week 10 to week 20**
- **Safety profile similar to that previously observed**
- **Phase 3 program in Crohn's disease to be initiated in 2016**

Mechelen, Belgium; 21 April 2016 – Galapagos NV (Euronext & NASDAQ: GLPG) reported 20-week results from its FITZROY study with the investigational, selective JAK1 inhibitor filgotinib in Crohn's disease.

174 patients with moderately to severely active Crohn's disease were enrolled in FITZROY, a double-blind, placebo-controlled Phase 2 study. Patients recruited were either anti-TNF naïve or anti-TNF failures. The study comprised two parts each of 10 weeks duration: the first part – reported in December 2015 - investigated the safety and efficacy of filgotinib 200 mg once daily versus placebo. The FITZROY study achieved the primary endpoint of clinical remission at 10 weeks: the percentage of patients achieving a Crohn's Disease Activity Index (CDAI) score lower than 150 was significantly higher in patients treated with filgotinib versus patients receiving placebo. Improvement in histopathology and endoscopy assessments were observed at Week 10. Further evaluation is ongoing.

The second part of the study investigated continued treatment through 20 weeks in an exploratory analysis that was not powered for statistical significance. Clinical responses continued from week 10 to week 20. Non-responders in the placebo arm from the first ten weeks received filgotinib 100 mg in the second ten weeks and showed improvement in clinical remission during the second part of the study.

There were no new safety signals during the second part of the FITZROY study, consistent with the profile of filgotinib previously described. Most common adverse events observed during this study were infections, gastrointestinal disorders and nervous system disorders. There were no gastrointestinal perforations, no cancers and no deaths reported during the study.

Galapagos and Gilead Sciences intend to submit the FITZROY 20-week results to future medical conferences.

"We are pleased by the outcome of the FITZROY study, positioning filgotinib as a potential oral treatment for patients with Crohn's disease. The observed safety profile of filgotinib further strengthens its promising efficacy," said Piet Wigerinck, Chief Scientific Officer at Galapagos. "We are proud to be advancing what could become the first new oral treatment for Crohn's disease in decades."

Galapagos and Gilead entered into a global partnership for the development and commercialization of filgotinib for inflammatory indications. Gilead intends to initiate a Phase 3 study with filgotinib in Crohn's disease later in 2016.

About Crohn's disease

Crohn's disease (CD) is an inflammatory bowel disease causing chronic inflammation of the gastrointestinal, or GI, tract with a relapsing and remitting course. The prevalence estimates for CD in North America range from 44 cases to 201 cases per 100,000 persons and in Europe, from 37.5 cases to 238 cases per 100,000 persons. The disease is slightly more common in women, with a peak incidence at the age of 20 to 40 years. The disease is characterized by inflammation that may affect any part of the GI tract from mouth to anus, but most commonly the distal small intestine and proximal colon, causing a wide variety of symptoms including anemia, abdominal pain, diarrhea, vomiting, and weight loss. The characteristic inflammatory response of CD is focal transmural inflammation, frequently associated with granuloma formation, which may evolve to progressive damage over time. Treatment of CD will depend on severity of the disease. The main goal of treatment is to reduce inflammation in the intestine, prevent flares and keep patients' disease in remission. While mild symptoms may respond to an antidiarrheal medicine, antibiotics, and other medicines to control inflammation, severe symptoms are often treated with anti-TNF agents. Anti-TNF agents, however, do not work for all patients, and, in patients who do find therapeutic benefit, they can lose their effect over time as a result of relapse.

About filgotinib

Filgotinib is an investigational, selective JAK1 inhibitor discovered and developed by Galapagos using its target and drug discovery technology platform. In addition to the promising efficacy and safety with filgotinib in Crohn's disease, filgotinib has also been studied in rheumatoid arthritis (RA) with over 700 patient years of experience. Galapagos and Gilead have a global partnership for the development and commercialization of filgotinib for inflammatory indications. Gilead is preparing to initiate a Phase 3 program with filgotinib in RA and Crohn's disease in 2016.

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.

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Galapagos Forward-Looking Statements

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