

First clinical centers opened for Phase 2 Crohn's study with GLPG0634

- **First selective JAK1 inhibitor to enter Phase 2 in Crohn's disease**
- **180 patients to be enrolled for 20 weeks of treatment**
- **Topline data expected in Q2 2015**
- **Galapagos eligible for \$50 M success fee from AbbVie upon study completion**

Mechelen, Belgium; 29 January 2014 - Galapagos NV (Euronext: GLPG) announced today that the first clinical centers have been opened for enrolment in the Phase 2 clinical study in Crohn's disease with GLPG0634, a selective JAK1 inhibitor. The Phase 2 study will evaluate the efficacy and safety of GLPG0634 during 20 weeks of treatment in 180 patients with active Crohn's disease.

GLPG0634 is the first selective JAK1 inhibitor in development for Crohn's disease. The innovative design of the Phase 2 study with GLPG0634 will evaluate induction of disease remission and explore early maintenance of its beneficial effects, potentially enabling a rapid entry into Phase 3 studies. Galapagos will fund and conduct the Phase 2 study in Crohn's disease, recruiting patients in approximately 49 clinical centers throughout Western and Eastern Europe. Upon successful completion of the Crohn's study, AbbVie will pay Galapagos \$50 million. Galapagos expects to read out topline results in Q2 2015. Full details of the study design can be found on www.clinicaltrials.gov.

"We are very pleased to announce the start of the Crohn's study with GLPG0634, the first selective JAK1 inhibitor in Phase 2 in Crohn's disease," said Dr Piet Wigerinck, Chief Scientific Officer of Galapagos. "Galapagos' pipeline has really matured. Patient studies in six different indications should deliver readouts within the next year or two, making for a truly data-rich period for Galapagos going forward."

The Phase 2 study in Crohn's disease will be performed in parallel with the Phase 2B program for GLPG0634 in rheumatoid arthritis (RA), which includes two dose-finding studies of 24 weeks of treatment in 875 moderate to severe RA patients refractory to methotrexate, and an open label extension study. Galapagos expects to report 12-week topline data from the Phase 2B RA program in Q4 2014, and 24-week data in Q1 2015. AbbVie has the exclusive right to license GLPG0634 upon completion of the Phase 2B RA studies.

About candidate drug GLPG0634

GLPG0634 is an orally-available, novel Janus kinase (JAK) inhibitor with selectivity for JAK1 developed by Galapagos. JAKs are critical components of signalling mechanisms utilized by a number of cytokines and growth factors, including those that are elevated in rheumatoid arthritis patients. JAK inhibitors have shown long-term efficacy in rheumatoid arthritis studies with an early onset of action. GLPG0634 differentiates from other JAK inhibitors in development by specifically targeting JAK1, a strategy which could result in a better efficacy and safety profile. GLPG0634 is a fully proprietary program. Upon successful completion of the Phase 2B studies in RA, AbbVie will pay \$200 million, license the program, and will assume sole responsibility for Phase 3 clinical development and global manufacturing. Galapagos will then be eligible to receive additional downstream milestones, plus tiered double-digit royalties on global commercial sales.

About Crohn's disease

Crohn's disease is a type of inflammatory bowel disease in which the well-controlled balance of the intestinal immune system is disturbed. The disease causes ulcerations of the small and large intestines in particular, but may affect any part of the digestive system from mouth to anus. The cause of the disease is unknown, with onset usually between the ages of 15 and 35. Patients suffer from abdominal pain, diarrhea (often bloody), vomiting, fever, and weight loss. There is no cure for Crohn's disease; treatment options today are restricted to controlling symptoms, maintaining remission, and preventing relapse by the use of drugs that suppress the inflammation or the immune system, antibiotics, and eventually surgical removal of the inflamed bowels. Driven by new therapies in development, Decision Resources estimates that the market for Crohn's disease treatment will grow from \$3.8 Billion in 2011 to \$5.6 Billion in 2021.

About Galapagos

[Galapagos](#) (Euronext: GLPG; OTC: GLPYY) is specialized in novel modes-of-action, with a large pipeline comprising of six Phase 2 studies (three led by GSK), one Phase 1 study, five pre-clinical, and 20 discovery small-molecule and antibody programs in cystic fibrosis, inflammation, antibiotics, metabolic disease, and other indications.

AbbVie and Galapagos signed an agreement in CF where they work collaboratively to develop and commercialize oral drugs that address two mutations in the CFTR gene, the G551D and F508del mutation. Potentiator GLPG1837 is at the pre-clinical candidate stage. In the field of inflammation, AbbVie and Galapagos signed a worldwide license agreement whereby AbbVie will be responsible for further development and commercialization of [GLPG0634](#) after Phase 2B. GLPG0634 is an orally-available, selective inhibitor of JAK1 for the treatment of rheumatoid arthritis and potentially other inflammatory diseases, currently in Phase 2B studies in RA and about to enter Phase 2 studies in Crohn's disease. Galapagos has another selective JAK1 inhibitor in Phase 2 in ulcerative colitis, psoriasis, and lupus, GSK2586184 (formerly GLPG0778, in-licensed by GlaxoSmithKline in 2012). [GLPG0974](#) is the first inhibitor of FFA2 to be evaluated clinically for the treatment of IBD; this program is currently in a Proof-of-Concept Phase 2 study. [GLPG1205](#) is a first-in-class molecule that targets inflammatory disorders and has completed Phase 1.

The Galapagos Group, including fee-for-service companies [BioFocus](#), [Argenta](#) and [Fidelta](#), has around 800 employees and operates facilities in five countries, with global headquarters in Mechelen, Belgium. Further information at: www.glpq.com

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Galapagos forward-looking statements

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