Galapagos announces GSK2586184 JAK1 molecule moves into Phase 2 for ulcerative colitis

Mechelen, Belgium; 27 November 2013 - Galapagos NV (Euronext: GLPG) announced today that GlaxoSmithKline plan to initiate an exploratory Phase 2 study with GSK2586184 (formerly GLPG0778) in patients with ulcerative colitis, a third indication for this investigational molecule, in addition to psoriasis and lupus.

GSK2586184 is a selective JAK1 inhibitor which was discovered and developed within Galapagos’ inflammation alliance with GSK. GSK in-licensed the molecule in February 2012, gaining worldwide rights to further development and commercialization. Galapagos is eligible, without further financial investment from Galapagos, to receive from GSK €34M in additional milestones, plus up to double-digit royalties on global commercial sales of all therapeutic indications of GSK2586184.

“Inhibition of Janus kinase (JAK) signalling proteins is considered a promising new therapeutic route to treat inflammatory diseases. Galapagos has discovered multiple JAK inhibition molecules, three of which have reached the clinic,” said Onno van de Stolpe, CEO of Galapagos.

The Phase 2 studies with GSK2586184 in ulcerative colitis, psoriasis, and lupus are scheduled to be completed in November 2014, March 2014, and November 2015, respectively. Further details of all three Phase 2 studies can be found on www.gsk.com and www.clinicaltrials.gov, under GSK2586184.

About ulcerative colitis
Ulcerative colitis is the most common inflammatory bowel disease worldwide. It is a disease of the colon (large intestine) characterized by bloody diarrhoea and there is often a disease pattern of gradual onset, spontaneous remission and subsequent relapses. Symptoms of frequent urgent diarrhoea, fatigue and abdominal pain can significantly reduce a patient’s quality of life and productivity.

About Galapagos
Galapagos (Euronext: GLPG; OTC: GLPYY) is specialized in novel modes-of-action, with a large pipeline comprising 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. 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 lupus, psoriasis, and ulcerative colitis, 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 is currently in a First-in-Human Phase 1 study.

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.glpg.com
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