

Galapagos opens IND for GLPG0634 in the US

Mechelen, Belgium; 3 December 2012 – Galapagos NV (Euronext: GLPG) announced today that it has opened its Investigational New Drug application for GLPG0634 with the US Food and Drug Administration.

Galapagos intends to conduct a Phase 1 drug interaction study in the United States, which is expected to be completed in the first quarter of 2013. Acceptance of the IND was based on a review by the FDA of the GLPG0634 data package, including chemical/pharmaceutical data, preclinical data up to the formal 13-week toxicology studies and currently completed clinical studies.

“This is an important step in our clinical development plan for GLPG0634” said Piet Wigerinck, CSO of Galapagos. “The FDA has reviewed all the GLPG0634 pre-clinical and clinical data to date and found these supportive of the conduct of our first clinical trial within the United States. We will follow up with studies in rheumatoid arthritis patients next year, and intend to include US study centers in our Phase 2b program.”

About Investigational New Drug (IND) Application

United States Federal law requires a pharmaceutical company to obtain an exemption to ship an experimental drug across state lines, usually to clinical investigators, before a marketing application for the drug has been approved. The IND is the means by which the sponsor technically obtains this exemption. The FDA reviews the IND for safety to assure that research subjects will not be subjected to unreasonable risk. The IND application contains information in three broad areas: animal pharmacology and toxicology studies, clinical protocols and investigator information, and manufacturing information.

About Galapagos

[Galapagos](#) (Euronext: GLPG; OTC: GLPYY) is a mid-size clinical stage biotechnology company specialized in the discovery and development of small molecule and antibody therapies with novel modes-of-action. The Company is progressing its JAK1 inhibitor GLPG0634, as well as one of the largest pipelines in biotech, with four programs in development and over 30 discovery programs. The Galapagos Group has over 800 employees and operates facilities in six countries, with global headquarters in Mechelen, Belgium. More info at: www.glpj.com

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