Orphan Drug Designation for GLPG1690 in systemic sclerosis

Mechelen, Belgium; 29 January 2020, 8.00 CET – Galapagos NV (Euronext & NASDAQ: GLPG) announces today that the US Food & Drug Administration (FDA) and the European Commission (EC) have granted investigational autotaxin inhibitor GLPG1690 'orphan drug designation' for the treatment of systemic sclerosis (SSc).

In order to stimulate the pharmaceutical industry to develop and market medicines for diseases affecting a small number of patients, the EC and the FDA offer a range of incentives to encourage the development of these 'orphan' medicines for rare diseases in the European Union and the United States. These incentives include amongst others 7 to 10 years of market exclusivity once the medicine is on the market, regulatory fee reductions and fee waivers and access to the centralized procedure for marketing authorization in Europe.[1,2]

"We are happy to see that the EC and FDA recognize GLPG1690 as a potential new treatment for SSc patients. With the NOVESA Phase 2 trial in SSc fully recruited, we expect to see topline data in the second half of the year," said Dr. Walid-Abi-Saab, CMO of Galapagos.

About SSc
Diffuse cutaneous systemic sclerosis (SSc) is an autoimmune disease involving multiorgan fibrosis, which has one of the highest mortality rates among rheumatic diseases.[3] One of the most visible manifestions is hardening of the skin. In diffuse cutaneous SSc, skin thickening affects several body areas, and patients have a higher risk of developing fibrosis of various internal organs, such as the lung. Currently, there are no approved drugs for this disease. SSc affects approximately 90,000 patients in the US and Europe, with a predominance of female patients (75%).

About GLPG1690
GLPG1690 is an investigational small molecule, selective autotaxin inhibitor that was inlicensed by Gilead Sciences, Inc. as part of the global R&D collaboration between Galapagos & Gilead. Autotaxin is the main enzyme responsible for lysophosphatidic acid (LPA) production. LPA is a well-known pro-fibrotic and pro-inflammatory lipid, acting through at least 6 g-protein coupled receptors. Galapagos identified the autotaxin target using its proprietary target discovery platform and developed molecule GLPG1690 as an inhibitor of this target. GLPG1690 is currently being studied in a global Phase 3 program in idiopathic pulmonary fibrosis (ISABELA) as well as in the NOVESA Phase 2 trial.

GLPG1690 is an investigational drug and its efficacy and safety have not been established by any regulatory agency.

For more information about GLPG1690: www.glpg.com/glpg-1690
For information about the studies with GLPG1690 in systemic sclerosis: www.clinicaltrials.gov

About Galapagos
Galapagos (Euronext & NASDAQ: GLPG) discovers and develops small molecule medicines with novel modes of action, three of which show promising patient results and are currently in late-stage development in multiple diseases. Galapagos' pipeline comprises discovery programs through Phase 3 programs in inflammation, fibrosis, osteoarthritis and other indications. The Company's ambition is to become a leading global biopharmaceutical company focused on the discovery, development and commercialization of innovative medicines.

[1] Source: www.ema.europe.eu
[2] Source: www.fda.gov
[3] Nikpour et al. *Curr Opin Rheumatol.* 2014

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Forward-looking statements

This release may contain forward-looking statements, including, among other things, statements regarding Galapagos' strategic ambitions, the mechanism of action and potential activity of GLPG1690, the anticipated timing of clinical trials with GLPG1690, the progression and results of such trials, future regulatory submissions and Galapagos' interactions with regulatory authorities. Galapagos cautions the reader that forward-looking statements are not guarantees of future performance. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition and liquidity, performance or achievements of Galapagos, or industry results, to be materially different from any historic or future results, financial conditions and liquidity, performance or achievements expressed or implied by such forward-looking statements. In addition, even if Galapagos' results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. Among the factors that may result in differences are that Galapagos' expectations regarding its GLPG1690 development program may be incorrect, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from Galapagos' ongoing clinical research programs may not support registration or further development of GLPG1690 due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties (including its collaboration partner for GLPG1690, Gilead), and estimating the commercial potential of GLPG1690. A further list and description of these risks, uncertainties and other risks can be found in Galapagos' Securities and Exchange Commission (SEC) filings and reports, including in Galapagos' most recent annual report on Form 20-F filed with the SEC and other filings and reports filed by Galapagos with the SEC. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. Galapagos expressly disclaims any obligation to update any such forward-looking statements in this document to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements, unless specifically required by law or regulation.