Galapagos initiates NOVESA Phase 2a trial in patients with systemic sclerosis

Mechelen, Belgium; 6 January 2019, 22.01 CET – Galapagos NV (Euronext & NASDAQ: GLPG) expands its clinical study program with GLPG1690 in systemic sclerosis, following the recent start of the ISABELA Phase 3 program with '1690 in IPF.

NOVESA is a double-blind, placebo-controlled Phase 2a trial evaluating the efficacy, safety and PK/PD of '1690 in patients with systemic sclerosis (SSc, or scleroderma). NOVESA is planned to recruit 30 patients with diffuse cutaneous SSc, an autoimmune disease involving multiorgan fibrosis, which has one of the highest mortality rates among rheumatic diseases[1]. 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%).

The primary endpoint of NOVESA is the modified Rodnan skin score (mRSS) at 24 weeks. mRRS measures the skin thickness as a surrogate measure of disease severity and mortality, with an increase in thickness associated with involvement of internal organs and increased mortality[2]. Secondary objectives and exploratory endpoints include FVC[3], HRCT[4], quality of life as measured by QoL-Q (SHAQ)[5], and CRISS[6], a SSc disease composite score.

"In addition to our Phase 3 program in IPF[7], we are excited to broaden our development program with '1690 to a second indication," said Dr. Walid Abi-Saab, Chief Medical Officer at Galapagos. "Moreover, SSc is particularly interesting, as this disease straddles our expertise in autoimmune diseases as well as in fibrosis. Thanks to the broad MoA of '1690, which is both anti-inflammatory and anti-fibrotic, this compound has the potential to address the important unmet medical need in SSc."

About '1690

GLPG1690 is a small molecule, selective autotaxin inhibitor which is fully proprietary to Galapagos. 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 '1690 as an inhibitor of this target. '1690 is currently being studied in a global Phase 3 program in IPF (ISABELA) as well as in a Phase 2 trial in SSc.

GLPG1690 is an investigational drug and its efficacy and safety have not been established.

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

[1] Nikpour et al. *Curr Opin Rheumatol.* 2014
[2] LeRoy et al. *J Rheumatol.* 2001; Dobrota et al. *Annals Rheum Dis.* 2016
[3] Forced Vital Capacity
[4] High-resolution computed tomography
[5] Scleroderma Health Assessment Questionnaire – Disability Index
[6] Combined Response Index of diffuse cutaneous Systemic Sclerosis
[7] Idiopathic Pulmonary Fibrosis

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. Our pipeline comprises Phase 3 through to discovery programs in inflammation, fibrosis, osteoarthritis, and other indications. Our ambition is to become a leading global biopharmaceutical company focused on the discovery, development and commercialization of innovative medicines. More information at www.glpg.com.

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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, 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.