

Galapagos completes recruitment of NOVESA trial in systemic sclerosis

Mechelen, Belgium; 5 December 2019, 22.01 CET – Galapagos NV (Euronext & NASDAQ: GLPG) has completed recruitment for the NOVESA Phase 2 clinical trial with GLPG1690.

NOVESA is a double-blind, placebo-controlled Phase 2a trial evaluating the efficacy, safety and PK/PD of GLPG1690 in patients with systemic sclerosis (SSc), an autoimmune disease involving multiorgan fibrosis which has one of the highest mortality rates among rheumatic diseases¹. NOVESA recruited 33 patients with diffuse cutaneous systemic sclerosis (dcSSc). One of the most visible manifestations is hardening of the skin. In dcSSc, the skin thickening is more widespread; these patients have a higher risk of developing fibrosis of multiple internal organs, including the lung. There are no approved drugs for this disease. SSc affects approximately 124,000 patients² in the US and Europe³, with a predominance of female patients (>80%).

The primary endpoint of NOVESA is the modified Rodnan Skin Score (mRSS) at 24 weeks. mRSS measures the skin thickness as a surrogate measure of disease severity and mortality in those with dcSSc. An increase in skin thickness is associated with involvement of internal organs and increased mortality⁴. Secondary and exploratory parameters include FVC⁵, HRCT⁶, safety and tolerability, quality of life as measured by QoL-Q (SHAQ)⁷, and CRISS⁸, a SSc disease composite score. Topline results from the NOVESA trial are expected in the second half of 2020. Patients completing the NOVESA study are offered the opportunity to roll over to a long-term extension trial.

"We are excited by the rapid enrollment into NOVESA and look forward to learning the results of GLPG1690's efficacy and safety in patients with SSc. We consider SSc as an important and complementary indication to idiopathic pulmonary fibrosis, where a global Phase 3 program is underway," said Dr Walid Abi-Saab, Chief Medical Officer of Galapagos. "Thanks to the broad mechanism of action of '1690, which we believe is both anti-inflammatory and anti-fibrotic, this compound has the potential to address the important unmet medical need in SSc."

About GLPG1690

GLPG1690 is a 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 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.glpq.com/glpq-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, several 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

¹ Nikpour et al. *Curr Opin Rheumatol*. 2014

² GlobalData

³ Europe includes FR,DE,IT,ES,UK only

⁴ LeRoy et al. *J Rheumatol*. 2001; Dobrota et al. *Annals Rheum Dis*. 2016

⁵ Forced Vital Capacity

⁶ High-resolution computed tomography

⁷ Scleroderma Health Assessment Questionnaire – Disability Index

⁸ Combined Response Index of diffuse cutaneous Systemic Sclerosis

focused on the discovery, development and commercialization of innovative medicines. More information at www.glpq.com.

Contacts

Investors:

Elizabeth Goodwin
VP Investor Relations
+1 781 460 1784

Sofie Van Gijssel
Director Investor Relations
ir@glpg.com

Media:

Carmen Vroonen
Senior Director Communications & Public Affairs
+32 473 824 874

Evelyn Fox
Director Communications
+31 6 53 591 999
communications@glpg.com

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.