Primary endpoint achieved with ziritaxestat in NOVESA trial in systemic sclerosis patients

Mechelen, Belgium; 11 September 2020, 04.30 CET – Galapagos NV (Euronext & NASDAQ: GLPG) reports positive topline results in the NOVESA Phase 2a clinical trial with investigational, ziritaxestat (GLPG1690) in patients with diffuse cutaneous systemic sclerosis (dcSSc).

Ziritaxestat reached the primary endpoint of the study with a statistically significant change from baseline in the modified Rodnan Skin Score (mRSS) at Week 24, of -8.3 vs -5.7 for placebo.

	600 mg ziritaxestat, n=21	**placebo, n=12**
Mean baseline mRSS (standard deviation)	27.0 (8.8)	22.5 (6.2)
Mean change from baseline (standard error) at Week 24, p-value[1]	-8.3 (1.2), p=0.0411	-5.7 (1.7)

NOVESA is a double-blind, placebo-controlled Phase 2a proof-of-concept trial evaluating the efficacy, safety and tolerability of ziritaxestat (GLPG1690) in 33 patients with dcSSc. DcSSc is a severe autoimmune disease with one of the highest mortality rates among rheumatic diseases[2] with no drugs currently approved to treat the overall disease. Systemic sclerosis (SSc) affects approximately 124,000 people[3] in the US and Europe[4], with a predominance of female patients (>80%).

Patients recruited for NOVESA included mostly females (70%) around 50 years old, with a mean disease duration of 1.9 years. Most patients enrolled were on a background immunosuppressant therapy during the course of the study.

Ziritaxestat was generally well tolerated. No deaths were reported in this study. Two patients taking ziritaxestat experienced serious adverse events versus one patient in the placebo group. Both patients in the ziritaxestat group recovered fully and are still participating in the long-term extension trial.

94% of patients (31 of the 33) who completed the NOVESA trial continued in the long-term open label extension trial.

"We are excited to see that after showing promising activity in the phase 2 FLORA trial in idiopathic pulmonary fibrosis, ziritaxestat achieved statistically significant improvements in mRSS in diffuse SSc, the primary endpoint in the NOVESA study. Keeping in mind that this is our first study in SSc and that the impact on skin is difficult to measure on a background treatment with immunosuppressants, we are pleased with the results reported today. We will now further analyze the NOVESA data to determine next steps in SSc, a disease with important unmet medical need," said Dr Walid Abi-Saab, Chief Medical Officer of Galapagos.

Detailed results from the NOVESA trial will be presented at future medical conferences.

Ziritaxestat is an investigational drug and not approved by any regulatory authority. Its efficacy and safety have not been established.

About ziritaxestat

Ziritaxestat is a small molecule, selective autotaxin inhibitor co-developed with Gilead Sciences, Inc. as part of the global 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

[1] P-value calculated based on least square means
[2] Nikpour et al. *Curr Opin Rheumatol.* 2014
[3] GlobalData
[4] Europe includes FR,DE,IT,ES,UK only

target discovery platform and developed molecule ziritaxestat as an inhibitor of this target. Ziritaxestat has orphan drug designation from the US and EU in both idiopathic pulmonary fibrosis (IPF) and SSc and is currently being studied in a global Phase 3 program in IPF (ISABELA), in addition to the ongoing NOVESA extension trial.

For more information about ziritaxestat: www.glpg.com/glpg-1690
For information about the studies with ziritaxestat 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 discovery through Phase 3 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 ziritaxestat the anticipated timing of clinical trials with ziritaxestat, 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 ziritaxestat 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 ziritaxestat due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties (including its collaboration partner for ziritaxestat, Gilead), and estimating the commercial potential of ziritaxestat. 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.