

Galapagos reports initiation of ISABELA Phase 3 program with GLPG1690 in patients with Idiopathic Pulmonary Fibrosis (IPF)

Mechelen, Belgium; 17 December 2018, 22.01 CET – Galapagos NV (Euronext & NASDAQ: GLPG) today announces that it has dosed its first patient in the worldwide ISABELA Phase 3 program with autotaxin inhibitor GLPG1690 in IPF.

“Today’s news again demonstrates our commitment to the rapid advancement of our IPF franchise, including the ISABELA and the PINTA trials. We are excited by the feedback received from participating sites and KOLs, which underscores the need for novel treatments to address the remaining high unmet need in IPF,” said Dr. Walid Abi-Saab, Chief Medical Officer at Galapagos.

About GLPG1690

GLPG1690 is a small molecule, selective autotaxin inhibitor which is fully proprietary to Galapagos. Galapagos identified the autotaxin target using its proprietary target discovery platform and developed molecule GLPG1690 as an inhibitor of this target. In the FLORA Phase 2a trial, patients on treatment with GLPG1690 showed improvement in forced vital capacity (FVC) at 12 weeks, with an encouraging safety profile. Galapagos received orphan drug designation for GLPG1690 in IPF from the US Food & Drug Administration (FDA) and European Commission (EC).

GLPG1690 is an investigational drug and its efficacy and safety have not been established. For more information about GLPG1690: www.glpq.com/glpq-1690

About IPF

IPF is a chronic, relentlessly progressive fibrotic disorder of the lungs that typically affects adults over the age of 40. There are approximately 200,000 patients with IPF in the US and Europe, and that number is expected to grow as diagnosis improves. The clinical prognosis of patients with IPF is poor, as the median survival at diagnosis is 2 to 4 years. Currently, no medical therapies have been found to cure IPF. The medical treatment strategy aims to slow the disease progression and improve the quality of life.

About ISABELA 1 & 2

The ISABELA Phase 3 program consists of two identically designed trials, ISABELA 1 and ISABELA 2, and will enroll a total of 1,500 IPF patients combined. Recruitment will be worldwide, with a significant proportion of patients in the US and Europe. Patients will continue on their standard of care and will be randomized to one of two doses of GLPG1690 or placebo. The primary endpoint will be the rate of decline of FVC (in mL) until week 52. Secondary assessments will include respiratory-related hospitalizations, mortality, quality of life, safety and tolerability.

All patients will continue on their treatment until the last patient in their respective study has completed 52 weeks of treatment. Therefore, some patients will remain in the study for substantially longer than 52 weeks. This approach will allow assessment of less frequent clinical events that are otherwise difficult to assess in conventional clinical studies of one-year duration.

For information about the ISABELA studies: www.clinicaltrials.gov (NCT03711162)

For more information about participation in the ISABELA program: www.isabelastudies.com

About PINTA

PINTA is a randomized, double-blind, placebo-controlled Phase 2 trial investigating a 100 mg once-daily oral dose of GLPG1205. The drug candidate or placebo will be administered for 26 weeks in up to 60 IPF patients. Patients may remain on their local standard of care as background therapy, whether or not they were previously or currently are treated with Esbriet^{®1} (pirfenidone) and Ofev^{®2} (nintedanib). The primary objective of the trial is to assess the change from baseline in Forced Vital Capacity (FVC in mL) over 26 weeks compared to placebo. Secondary measures include safety, tolerability, pharmacokinetics and pharmacodynamics, time to major events, changes in functional exercise capacity, and quality of life. Recruitment for PINTA is planned in 10 countries in Europe, North Africa, and the Middle East.

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.glp.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 and GLPG1205, the anticipated timing of clinical trials with GLPG1690 and GLPG1205, 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 and GLPG1205 development programs 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 and GLPG1205 due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties, and estimating the commercial potential of GLPG1690 and GLPG1205. A further list and description of these risks, uncertainties and other risks can be found in

¹ Esbriet[®] (pirfenidone) is an approved drug for IPF, marketed by Roche/Genentech

² Ofev[®] (nintedanib) is an approved drug for IPF, marketed by Boehringer Ingelheim

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.