

Galapagos completes recruitment of PINTA trial in idiopathic pulmonary fibrosis

Mechelen, Belgium; 13 January 2020, 7.30 CET — Galapagos NV (Euronext & NASDAQ: GLPG) has completed recruitment for the PINTA Phase 2 clinical trial with oral GPR84 inhibitor GLPG1205.

PINTA is a randomized, double-blind, placebo-controlled Phase 2 trial investigating a 100 mg once-daily oral dose of GLPG1205 in more than 60 patients with idiopathic pulmonary fibrosis (IPF).

"We are happy with the progress made in our PINTA trial, with recruitment completed ahead of schedule, and look forward to learning more about GLPG1205 in IPF," said Dr. Walid Abi-Saab, Chief Medical Officer at Galapagos. "We are strongly committed to the rapid development of our IPF portfolio, including the worldwide Phase 3 ISABELA program that we are executing with our collaboration partner Gilead, to address this important unmet medical need."

About GLPG1205

GLPG1205, fully proprietary to Galapagos, is a small molecule selectively antagonizing GPR84. Galapagos identified the GPR84 target using its proprietary target discovery platform and developed GLPG1205 as an antagonist of this target. GLPG1205 showed promising results in relevant pre-clinical models for IPF, and there is growing evidence in scientific literature and in clinical research that GPR84 plays a role in this disease. GLPG1205 successfully completed several Phase 1 trials, showing favorable findings relating to tolerability and target engagement in healthy volunteers. GLPG1205 is an investigational drug and its efficacy and safety have not yet been established.

For information about the studies with GLPG1205: www.clinicaltrials.gov (NCT03725852) For more information about GLPG1205: www.qlpq.com/ipf

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 250,000 patients with IPF in the U.S. and Europe. As such, IPF is considered a rare disease. 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 current medical treatment strategy aims to slow the disease progression and improve the quality of life.

About the PINTA trial

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 more than 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. Patients in the PINTA trial were recruited in 9 countries in Europe and the Middle East.

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. Galapagos' pipeline comprises Phase 3 through to discovery 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 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



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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 GLPG1205, the anticipated timing, recruitment or enrollment of clinical trials with 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 quarantees 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 GLPG1205 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 GLPG1205 due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties, and estimating the commercial potential of GLPG1205. 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.