Galapagos reports positive topline results with GLPG1205 in IPF patients in PINTA Proof-of-Concept trial

- **Placebo-adjusted improvement in forced vital capacity (FVC) decline of 42mL across treatment groups at 26 weeks**
- **Correlation between FVC decline and pulmonary lobar volume change observed, as measured by functional respiratory imaging (FRI)**
- **GLPG1205 planned to progress to dose finding Phase 2b study**

Mechelen, Belgium; 30 November 2020, 22.01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) announces positive topline results with its investigational GPR84 antagonist GLPG1205 in Proof-of-Concept Phase 2 trial in idiopathic pulmonary fibrosis (IPF) patients.

The PINTA trial was a randomized, double-blind, placebo-controlled trial investigating a 100mg once-daily oral dose of GLPG1205. The study recruited and included a total of 68 IPF patients. Participants were administered drug candidate or placebo (2:1 randomization) for 26 weeks and could remain on their standard of care as background therapy, i.e. nintedanib, pirfenidone or neither. The primary objective of the trial was to assess the change from baseline in FVC (in mL) over 26 weeks compared to placebo. Other measures included safety, tolerability, time to major events, changes in functional exercise capacity, quality of life, pharmacokinetics, pharmacodynamics and FRI.

At week 26, patients receiving GLPG1205 on top of standard of care showed a smaller FVC decline, with a difference of 42mL versus placebo on top of standard of care (-76mL on placebo; -34mL on treatment). The study was not powered to show statistical significance. The FVC trend was consistent across the three treatment strata. In addition, the change in pulmonary lobar volume, as measured by FRI, correlates with the FVC decline observed.

No relevant safety signals were observed for GLPG1205 alone and on top of pirfenidone. The most frequently reported adverse events on GLPG1205 alone were gastrointestinal disorders, especially nausea. In the treatment arm of GLPG1205 on top of nintedanib, a higher rate of early discontinuations and high grade TEAEs were observed. In the arm of the study with GPLG1205 on top of nintedanib, there was one death due to an exacerbation of IPF, which was determined to be unrelated to study treatment.

Based on the results of this trial, Galapagos plans to progress GLPG1205 in a dose finding Phase 2b trial.

The full results of the PINTA trial will be submitted to a future medical conference and peer-reviewed medical journals.

"Keeping in mind the limitations of this early clinical study, the PINTA study with GLPG1205 is a positive trial. The consistent changes observed across treatment strata, using different analytical methods, including FRI, are very encouraging. While we need to understand more about long-term tolerability of the drug, the PINTA results warrant further investigation," said Prof. Dr. Toby Maher, Professor of Medicine at Keck School of Medicine, University of Southern California.

"We wish to thank participating patients and physicians in the PINTA trial. We are pleased to see a second novel mechanism of action from our innovative platform show early signs of activity in IPF, a highly fatal disease for which improved therapies are desperately needed. This additional novel mode of action may complement the anti-fibrotic approaches within our expanding IPF portfolio," said Dr. Piet Wigerinck, Chief Scientific Officer of Galapagos.

About GLPG1205 and the fibrosis portfolio
GLPG1205 is a small molecule selectively functionally antagonizing GPR84. Galapagos identified the GPR84 target using its proprietary target discovery platform. GLPG1205 showed promising results in relevant pre-clinical models for IPF. Galapagos currently has several drug candidates with distinct mechanisms of action in its portfolio aimed at building a fibrosis franchise, including ziritaxestat (GLPG1690, autotaxin inhibitor) in the ISABELA Phase 3 program in IPF, ziritaxestat in the NOVESA Phase 2 trial in systemic sclerosis, GLPG1205, GLPG4716 (chitinase receptor inhibitor) preparing for Phase 2 in IPF, and GLPG4124 and GLPG4586, currently in pre-clinical development.

GLPG1205 is investigational; its efficacy and safety have not been evaluated by any regulatory authority.
Information about studies with GLPG1205: www.clinicaltrials.gov
For more information about GLPG1205: www.glpg.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 200,000 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 around 3 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 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. The company's pipeline comprises early discovery through to Phase 3 programs in inflammation, fibrosis, and other indications. Galapagos' 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 press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, that are subject to risks, uncertainties and other factors that could cause actual results to differ materially from those referred to in the forward-looking statements and, therefore, the reader should not place undue reliance on them. These risks, uncertainties and other factors include, without limitation, the risk that ongoing and future clinical studies with GLPG1205 and other drug candidates from Galapagos' fibrosis portfolio may not be completed in the currently envisaged timelines or at all, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from the ongoing and planned clinical research programs may not support registration or further development of GLPG1205 and other drug candidates from Galapagos' fibrosis portfolio due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties and that Galapagos' estimations regarding its GLPG1205 and fibrosis portfolio development program and regarding the commercial potential of GLPG1205 and of other drug candidates from Galapagos' fibrosis portfolio, may be incorrect, as well as those risks and uncertainties identified in our Annual Report on Form 20-F for the year ended 31 December 2019 and our subsequent filings with the SEC. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The forward-looking statements contained herein are based on management's current expectations and beliefs and speak only as of the date hereof, and Galapagos makes no commitment to update or publicly release any revisions to forward-looking statements in order to reflect new information or subsequent events, circumstances or changes in expectations.