

## **Galapagos announces design for PINTA Phase 2 trial with GLPG1205 in IPF**

**Mechelen, Belgium; 9 July 2018; 7.30 CET – Galapagos NV (Euronext & NASDAQ: GLPG) announces the PINTA Phase 2 trial design with its GPR84 inhibitor GLPG1205 in patients with idiopathic pulmonary fibrosis (IPF).**

PINTA is a randomized, double-blind, placebo-controlled 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. 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. IPF diagnosis will be confirmed by central reading. Recruitment for PINTA is planned in 10 countries in Europe, North Africa, and the Middle East. First dosing of an IPF patient is expected in the second half of 2018.

GLPG1205 is a GPR84 inhibitor discovered by Galapagos and fully proprietary to Galapagos. GLPG1205 showed a reduction in signs and symptoms in IPF animal models and has shown favorable tolerability in healthy volunteers and ulcerative colitis patients in previous trials. Galapagos currently has three drug candidates with distinct mechanisms of action in its fully proprietary portfolio aimed at building an IPF franchise: GLPG1690 in the ISABELA Phase 3 program, GLPG1205 in PINTA Phase 2, and GLPG3499, currently in pre-clinical development.

"GLPG1205 has shown signs of good activity in relevant animal models, and GPR84 has already been validated as a mechanism in combination with nintedanib<sup>1</sup> in IPF," added Dr. Piet Wigerinck, Chief Scientific Officer of Galapagos. "We have a well-designed trial with PINTA for '1205 that we anticipate will give us new insights into the potential value of GPR84 inhibition as a mechanism to treat this highly fatal disease."

### **About GLPG1205**

GLPG1205 is a small molecule selectively inhibiting GPR84, which is fully proprietary to Galapagos. Galapagos identified the GPR84 target using its proprietary target discovery platform and developed molecule GLPG1205 as an inhibitor 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 a Phase 1 trial in 2013, showing favorable findings relating to safety and tolerability, and target engagement in healthy volunteers. GLPG1205 showed good tolerability but no activity in ulcerative colitis patients in 2016. GLPG1205 is an investigational drug and its efficacy and safety have not been established.

For information about the studies with GLPG1205: [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (posting expected in Q3 '18)  
For more information about GLPG1205: [www.glpg.com/ipf](http://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 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.

Regulatory agencies have approved Esbriet<sup>®2</sup> (pirfenidone) and Ofev<sup>®</sup> (nintedanib) for the treatment of IPF. Both pirfenidone and nintedanib have been shown to slow the rate of lung function decline in

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<sup>1</sup> Ofev<sup>®</sup> (nintedanib) is indicated for the treatment of IPF by Boehringer Ingelheim.

<sup>2</sup> Esbriet<sup>®</sup> (pirfenidone) is indicated for the treatment of IPF by Roche/Genentech.

IPF and are gaining ground as the standard of care worldwide. These regulatory approvals represent a major breakthrough for IPF patients; yet neither drug improves lung function, and the disease continues to progress in the majority of patients despite treatment. Moreover, the adverse effects associated with these therapies include diarrhea, liver function test abnormalities with nintedanib, nausea and rash with pirfenidone. Therefore, there is still a large unmet medical need as IPF remains a major cause of morbidity and mortality.

### **About Galapagos**

Galapagos (Euronext & NASDAQ: GLPG) is a clinical-stage biotechnology company specialized in the discovery and development of small molecule medicines with novel modes of action. Galapagos' pipeline comprises Phase 3 through to discovery programs in cystic fibrosis, inflammation, fibrosis, osteoarthritis and other indications. Our target discovery platform has delivered three novel mechanisms showing promising patient results in, respectively, inflammatory diseases, idiopathic pulmonary fibrosis and atopic dermatitis. Galapagos is focused on the development and commercialization of novel medicines that will improve people's lives. The Galapagos group, including fee-for-service subsidiary Fidelta, has approximately 640 employees, operating from its Mechelen, Belgium headquarters and facilities in the Netherlands, France, Switzerland, the US and Croatia. More information at [www.glpg.com](http://www.glpg.com).

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### **Forward-looking statements**

*This release may contain forward-looking statements, including statements regarding Galapagos' strategic ambitions, the potential activity of GLPG1205, the anticipated timing of future clinical studies with GLPG1205, the progression and results of such studies, and Galapagos' interactions with regulatory authorities, and statements regarding the current landscape of IPF treatments, including Esbriet® (pirfenidone) and Ofev® (nintedanib), and the unmet medical need for IPF treatments. 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 the inherent uncertainties associated with competitive developments, (including with respect to Esbriet® (pirfenidone) and Ofev® (nintedanib)), 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 due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties, and estimating the commercial potential of Galapagos' product candidates. 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 subsequent 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.*