

## **Galapagos initiates a Phase 2a study with GLPG1690 in idiopathic pulmonary fibrosis patients**

**Mechelen, Belgium; 6 April 2016 – Galapagos NV (Euronext & NASDAQ: GLPG) announced the start of its exploratory Phase 2a study with GLPG1690 in idiopathic pulmonary fibrosis (IPF) patients, named FLORA.**

FLORA is a randomized, double-blind, placebo-controlled study investigating a once daily oral dose of GLPG1690 administered for 12 weeks in 24 IPF patients. Primary objectives of the study are to assess safety, tolerability, pharmacokinetics and pharmacodynamics of GLPG1690 in an IPF patient population. Target engagement will be measured by LPA in plasma and bronchoalveolar lavage fluid, both at baseline and through twelve weeks of treatment. Secondary objectives include the evaluation of lung function, changes in disease biomarkers and quality of life. Galapagos expects to complete patient recruitment before end 2016, and to report topline results in Q2 2017.

GLPG1690 is a small molecule inhibitor of autotaxin and fully proprietary to Galapagos.

"We identified the autotaxin target using our proprietary target discovery platform and developed molecule GLPG1690 as an inhibitor of this target. GLPG1690 shows promising results in relevant pre-clinical models for IPF, and there is growing evidence in scientific literature that autotaxin plays a role in this disease. We are pleased to be able to investigate the effect of GLPG1690 in IPF patients and look forward to seeing the results in the first half of next year," said Dr Piet Wigerinck, Chief Scientific Officer of Galapagos.

### **About IPF**

IPF is a chronic, relentlessly progressive fibrotic disorder of the lungs that typically affects adults over the age of 40. According to an April 2013 GlobalData EpiCast report, the prevalence of IPF is <30 per 100,000 persons in both Europe and the United States, and as such, IPF is considered a rare disease. The clinical prognosis of patients with IPF is poor as the median survival at diagnosis is 2–5 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. Lung transplantation may be an option for appropriate patients with progressive disease and minimal comorbidities.

Regulatory agencies have approved Esbriet<sup>®1</sup> (pirfenidone) and Ofev<sup>®2</sup> (nintedanib) for the treatment of IPF. Both pirfenidone and nintedanib have been shown to slow the rate of lung function decline in IPF and are likely to become 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.

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<sup>1</sup> Esbriet<sup>®</sup> (pirfenidone) is indicated for the treatment of idiopathic pulmonary fibrosis (IPF) by Roche/Genentech.

<sup>2</sup> Ofev<sup>®</sup> (nintedanib) is indicated for the treatment of idiopathic pulmonary fibrosis (IPF) by Boehringer Ingelheim.

## 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. Our maturing pipeline comprises Phase 2, Phase 1, pre-clinical candidates and discovery studies in cystic fibrosis, inflammation, fibrosis, osteoarthritis and other indications. We have discovered and developed filgotinib: in collaboration with Gilead we aim to bring this JAK1-selective inhibitor for inflammatory indications to patients all over the world. 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 440 employees, operating from its Mechelen, Belgium headquarters and facilities in The Netherlands, France, and Croatia. More information at [www.glpq.com](http://www.glpq.com).

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### **Forward-Looking Statements**

*This release may contain forward-looking statements, including statements regarding the anticipated timing of clinical studies with GLPG1690 and the progression and results of such studies. 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 GLPG1690, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements, 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' 20-F filing for 2015 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.*