

GLPG1690 results in IPF published in The Lancet Respiratory Medicine and presented at ATS

Mechelen, Belgium; 20 May 2018; 20.30 CET; Galapagos NV (Euronext & NASDAQ: GLPG) announces publication milestones on GLPG1690 in idiopathic pulmonary fibrosis (IPF). In addition to presenting three abstracts on investigational drug GLPG1690 at the American Thoracic Society Meeting (ATS) from 18 to 23 May in San Diego, California, USA, Galapagos announces the publication of the FLORA Phase 2a study results in the most recent issue of The Lancet Respiratory Medicine.

"Safety, tolerability, pharmacokinetics, and pharmacodynamics of GLPG1690, a novel autotaxin inhibitor, to treat idiopathic pulmonary fibrosis: a phase 2a randomised placebo-controlled trial (FLORA trial)," by Prof. Dr. Toby Maher *et al.* describes the FLORA trial results and was published today in The Lancet Respiratory Medicine.

FLORA was an exploratory, randomized, double-blind, placebo-controlled trial investigating a once-daily oral dose of GLPG1690. The drug candidate was administered for 12 weeks in 23 IPF patients, 17 of whom received GLPG1690 and 6 of whom received placebo. Over the 12-week period, patients receiving GLPG1690 showed an FVC increase of 8 mL, while patients on placebo showed an FVC reduction of 87 mL (mean from baseline). GLPG1690 was well-tolerated by IPF patients in the FLORA trial.

"Although not without limitations, proof of concept studies are vital in addressing the huge unmet need for effective and well tolerated therapies for idiopathic pulmonary fibrosis, a progressive and inevitably fatal lung disease. Studies such as FLORA quickly support proof-of-concept of new treatment options, without unnecessarily exposing high-risk patients to investigational therapies of unknown efficacy for prolonged periods of time," said Dr. Toby Maher, British Lung Foundation Chair in Respiratory Research and Professor of Interstitial Lung Disease, Imperial College, London, in The Lancet Respiratory Medicine publication. "Although measuring effect of treatment was only a secondary, non-powered endpoint, the data from FLORA, particularly for FVC, are extremely encouraging and warrant further larger scale trials." A link to this publication can be found at www.glpg.com/glpg-1690.

At ATS in San Diego, the Galapagos team are in de midst of presenting the following abstracts:

Sunday May 20, 2018 9:15 AM - 4:15 PM - poster session

9869 - Pharmacodynamics and Pharmacokinetics of the Autotaxin Inhibitor GLPG1690 in the FLORA Trial: a Randomized, Placebo-controlled, Double Blind Phase IIa Clinical Trial of 12 Weeks in Individuals with Idiopathic Pulmonary Fibrosis

Sunday May 20, 2018 2:15 PM-4:15 PM – oral presentation

9097 - Randomized, Placebo-Controlled, Double Blind Phase IIa Clinical Trial to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of 12 Weeks of Treatment of an Autotaxin Inhibitor (GLPG1690) in Individuals with Idiopathic Pulmonary Fibrosis (FLORA Trial)

Tuesday May 22, 2018 2:15 PM - 4:15 PM - oral presentation

8893 - Assessment of the Effects of GLPG1690 in Idiopathic Pulmonary Disease (IPF) Patients Using Functional Respiratory Imaging (FRI)

More information can be found on <u>http://conference.thoracic.org</u>. All posters and presentations can be downloaded starting on 23 May from <u>www.glpg.com/glpg-1690</u>.

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. Oral investigational drug GLPG1690 showed 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. GLPG1690 appeared to halt disease progression as measured by FVC at 12 weeks and was well-tolerated by IPF patients in the FLORA Phase 2a trial reported in August 2017. Galapagos received orphan drug designation for GLPG1690 in IPF from the U.S. Food & Drug Administration (FDA) and European Commission (EC). In April 2018, Galapagos announced the design of a worldwide Phase 3 program, based on feedback from the FDA and the European Medicines Agency (EMA), to evaluate GLPG1690 in IPF patients. The planned ISABELA Phase 3 program with GLPG1690 is intended to support both New Drug Application (NDA) and Market Authorization Application (MAA) submissions in respectively the United States and European Union. GLPG1690 is an investigational drug and its efficacy and safety have not been established.

Preliminary information for patients and healthcare professionals can be found at <u>www.isabelastudies.com</u>. For more information about GLPG1690: <u>www.glpg.com/glpg-1690</u>.

About IPF

IPF is a chronic, relentlessly progressive fibrotic disorder of the lungs that typically affects adults over the age of 40. IPF affects approximately 200,000 patients in the United States and Europe and, as such, we have received orphan designation for our product candidate GLPG1690 in IPF from the European Commission and from the FDA. The clinical prognosis of patients with IPF is poor, as survival at diagnosis is two to four years. Currently, no medical therapies have been found to cure IPF. The medical treatment strategy aims to slow disease progression and improve quality of life. Lung transplantation may be an option for appropriate patients with progressive disease and minimal comorbidities.

Regulatory agencies have approved Esbriet^{®1} (pirfenidone) and Ofev^{®2} (nintedanib) for the treatment of mild to moderate IPF. Both Esbriet and Ofev have been shown to slow the rate of functional decline in IPF and are gaining ground as the standard of care worldwide. Combined sales of both drugs reached \$1.1 billion in 2016, with 74% of global revenues being in the United States. These regulatory approvals represent a major breakthrough for IPF patients; yet the disease in most patients on these therapies continues to progress. Therefore, there is still a large unmet medical need as IPF remains a major cause of morbidity and mortality. We estimate global sales of approved IPF drugs will grow to nearly \$5 billion in 2025.

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 634 employees, operating from its Mechelen, Belgium headquarters and facilities in the Netherlands, France, Switzerland, the United States and Croatia. More information available at www.glpq.com.

¹ Esbriet® (pirfenidone) is indicated for the treatment of IPF by Roche/Genentech.

² Ofev® (nintedanib) is indicated for the treatment of IPF 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 GLPG1690, the anticipated timing of future clinical trials with GLPG1690, the progression and results of such trials, 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 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 GLPG1690 due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties, and estimating the commercial potential of GLPG1690. 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.