

Galapagos announces ISABELA Phase 3 program in IPF

Mechelen, Belgium; 12 April 2018, 22.01 CET – Galapagos announces the design of a worldwide Phase 3 program, based on feedback from the FDA and EMA, to evaluate GLPG1690 in patients with idiopathic pulmonary fibrosis. 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 USA and EU.

The global Phase 3 program is expected to consist of two identically designed trials, ISABELA 1 and ISABELA 2. These will enroll patients diagnosed with IPF on top of their local standard of care, whether or not they were previously or currently are treated with Esbriet^{®1} (pirfenidone) and Ofev^{®2} (nintedanib). Recruitment will be worldwide, with a significant proportion of patients in the USA and Europe. This Phase 3 program is expected to start dosing in the second half of 2018.

ISABELA 1 and 2 are planned as confirmatory trials and will enroll a total of 1,500 IPF patients combined; patients will continue on their standard of care and will be randomized to one of two doses of the oral investigational drug GLPG1690 or placebo. The primary endpoint will be the rate of decline of FVC³ (in mL) until week 52. Secondary assessments will include respiratory-related hospitalizations, mortality, quality of life, safety and tolerability.

All patients will continue on their treatment until the last patient in their respective study has completed 52 weeks of treatment. Therefore, some patients will remain in the study for substantially longer than 52 weeks. This approach will allow assessment of less frequent clinical events that are otherwise difficult to assess in conventional clinical studies of one-year duration.

"We are gratified to have feedback on the registrational Phase 3 program from both the FDA and EMA in a broad IPF population. ISABELA is aimed at providing information to support application for a broad label in IPF patients, potentially including monotherapy and add-on. We look forward to starting ISABELA 1 and 2 trials to provide robust answers on efficacy and safety of GLPG1690, an investigational IPF treatment with an innovative mode of action," said Dr. Walid Abi-Saab, Chief Medical Officer. "Today's announcement also marks another landmark in our company's development; we will initiate our first Galapagos-sponsored Phase 3 development program."

Galapagos will present three abstracts on GLPG1690 at the American Thoracic Society Meeting in San Diego in May 2018.

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

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.

³ FVC=forced vital capacity

in IPF from the U.S. Food & Drug Administration (FDA) and European Commission (EC). GLPG1690 is an investigational drug and its efficacy and safety have not been established.

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

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® (pirfenidone) and Ofev® (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 neither drug improves lung function, and the disease in most patients on these therapies continues to progress. Moreover, the adverse effects associated with these therapies are considerable (e.g., diarrhea, liver function test abnormalities with Ofev, nausea and rash with Esbriet). 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 600 employees, operating from its Mechelen, Belgium headquarters and facilities in the Netherlands, France, Switzerland, the United States and Croatia. More information at www.glpg.com.

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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.