

Orphan Drug Designation in European Union for GLPG1690 in idiopathic pulmonary fibrosis

Mechelen, Belgium; 6 September 2016: Galapagos (Euronext & NASDAQ: GLPG) announces today that the European Commission (EC) has granted GLPG1690 'orphan drug designation' for the treatment of patients with idiopathic pulmonary fibrosis (IPF).

IPF is a chronic progressive fibrotic disorder of the lungs that typically affects adults over the age of 40. The prevalence of IPF is fewer than 30 per 100,000 persons in both Europe and the United States, and as such, IPF is considered a rare disease. Currently, no medical therapies have been found to cure IPF.

In order to stimulate the pharmaceutical industry to develop and market medicines for a small number of patients, the EC offers a range of incentives to encourage the development of these 'orphan' medicines for rare diseases in the European Union. These incentives include protocol assistance, i.e. scientific advice specific for designated orphan medicines, and 10 years of market exclusivity once the medicine is on the market. Orphan designated medicinal products also benefit from regulatory fee reductions and access to the centralized procedure for marketing authorization.¹

"We are happy to see that the EC recognizes the potential of GLPG1690 as a new treatment for IPF-patients in Europe. Next step will be the application for orphan drug designation with the Food and Drug Administration (FDA) in the US," said Piet Wigerinck, CSO of Galapagos.

GLPG1690 is currently being investigated in FLORA, a randomized, double blind, placebo-controlled Phase 2a study for 12 weeks in 24 IPF patients. Galapagos expects to report topline results in Q2 2017. GLPG1690 is a small molecule inhibitor of autotaxin and is fully proprietary to Galapagos.

Today at 16.30 CET hours, Galapagos is presenting 'Strong reversal of the lung fibrosis disease signature by autotaxin inhibitor GLPG1690 in a mouse model for IPF' at the European Respiratory Society Congress in London.

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 disease progression and improve the quality of life. Lung transplantation may be an option for appropriate patients with progressive disease and minimal comorbidities.

¹ Source: www.ema.europa.eu

Regulatory agencies have approved Esbriet^{®2} (pirfenidone) and Ofev^{®3} (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.

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 pipeline comprises Phase 3, 2, 1, pre-clinical 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 460 employees, operating from its Mechelen, Belgium headquarters and facilities in The Netherlands, France, and Croatia. More information at www.glpg.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, and the status and outcome of interactions with regulators. 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, clinical trial and product development activities and regulatory approval requirements (including that data from the ongoing clinical trial with GLPG1690 may not support registration or further development of GLPG1690 due to safety, efficacy or other reasons), 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 20-F filing 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

² Esbriet[®] (pirfenidone) is indicated for the treatment of idiopathic pulmonary fibrosis (IPF) by Roche/Genentech.

³ Ofev[®] (nintedanib) is indicated for the treatment of idiopathic pulmonary fibrosis (IPF) by Boehringer Ingelheim.



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