

## **Galapagos initiates Phase 1 study with cystic fibrosis drug GLPG2737**

*Triggers \$10 million milestone payment in collaboration with AbbVie*

**Mechelen, Belgium; 28 November 2016 – Galapagos NV (Euronext & NASDAQ: GLPG) reports the initiation of a Phase 1 study in healthy volunteers with GLPG2737, a novel C2 corrector drug for cystic fibrosis. Initiation of the Phase 1 study triggers a \$10 million milestone payment from AbbVie.**

The aim of the Phase 1 study is to evaluate the safety, tolerability and pharmacokinetics of oral single and multiple ascending doses of GLPG2737. The randomized, double-blind, placebo controlled, single centre study is being conducted in at least 64 healthy volunteers in the Netherlands. In the first part of the study, single ascending doses will be evaluated. In the second part, multiple ascending doses will be administered daily for 14 days. Topline results from this Phase 1 study with GLPG2737 are expected in the second quarter of 2017.

In order to bring a more effective therapy to the majority of cystic fibrosis patients, Galapagos and AbbVie are developing a portfolio of candidates addressing three complementary components for a potential combination therapy. Novel C2 corrector GLPG2737 is the first of multiple C2 correctors being developed and is the final component needed to complete a first triple combination; this drug initiating a Phase 1 safety study marks a significant step in the progress of the companies' cystic fibrosis triple combination portfolio development. Potentiators GLPG1837 and GLPG2451 and C1 corrector GLPG2222 are already being tested in the clinic.

Triple combinations of CF compounds in the portfolio have consistently shown restoration of healthy activity levels in *in vitro* assays with human bronchial epithelial (HBE) cells of patients with the F508del mutation. These combinations result in an increase in chloride transport compared to Orkambi<sup>1</sup> in HBE cells with the homozygous F508del mutation.

"We are pleased to initiate a Phase 1 study with the first of our C2 correctors for cystic fibrosis," said Dr Piet Wigerinck, CSO of Galapagos. "This step brings us closer to our goal of initiating a patient evaluation of a triple combination therapy by mid-2017."

### **About the Galapagos-AbbVie collaboration in cystic fibrosis**

In September 2013 Galapagos and AbbVie entered into a global collaboration agreement focused on the discovery and worldwide development and commercialization of potentiator and corrector molecules for the treatment of CF. Under the terms of the agreement, AbbVie made an upfront payment of \$45 million to Galapagos. Upon successful completion by Galapagos of clinical development through to completion of Phase 2, AbbVie will be responsible for Phase 3, with financial contribution by Galapagos. Galapagos has earned \$30 million in milestone payments to date and is eligible to receive up to approximately \$600 million in total payments for developmental and regulatory milestones, sales milestones upon the achievement of minimum annual net sales thresholds and additional tiered royalty payments on net sales, ranging from mid-teens to 20%.

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<sup>1</sup> Orkambi<sup>®</sup> is a prescription medicine sold by Vertex Pharmaceuticals, used for the treatment of cystic fibrosis (CF) in patients age 12 years and older who have two copies of the *F508del* mutation (*F508del/F508del*) in their *CFTR* gene.

Galapagos has commercial rights to China and South Korea, and has an option to co-promote in Belgium, Netherlands, and Luxembourg.

### **About cystic fibrosis (CF)**

CF is a rare, life-threatening, genetic disease that affects approximately 80,000 patients worldwide and approximately 30,000 patients in the United States. CF is a chronic disease that affects the lungs and digestive system. CF patients, with significantly impaired quality of life, have an average lifespan approximately 50% shorter than the population average, with the median age of death at 40. There currently is no cure for CF. CF patients require lifelong treatment with multiple daily medications, frequent hospitalizations and ultimately lung transplant, which is life-extending but not curative. CF is caused by a mutation in the gene for the CFTR protein, which results in abnormal transport of chloride across cell membranes. Transport of chloride is required for effective hydration of epithelial surfaces in many organs of the body. Normal CFTR channel moves chloride ions to outside of the cell. Mutant CFTR channel does not move chloride ions, causing sticky mucous to build up on the outside of the cell. CFTR dysfunction results in dehydration of dependent epithelial surfaces, leading to damage of the affected tissues and subsequent disease, such as lung disease, malabsorption in the intestinal tract and pancreatic insufficiency.

### **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 a pipeline of Phase 3, Phase 2, Phase 1, pre-clinical, and discovery programs 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 480 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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*This press release contains inside information within the meaning of Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (market abuse regulation).*

### **Forward-looking statements**

*This release may contain forward-looking statements, including statements regarding the potential efficacy of Galapagos' compounds in cystic fibrosis, the anticipated timing of clinical studies with the cystic fibrosis portfolio of drugs, 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 the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from the ongoing and planned clinical research programs in cystic fibrosis may not support registration or further development of a potential triple combination due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties (including its collaboration partner for cystic fibrosis, AbbVie), 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.*