

## **Galapagos doses first patient with novel CF corrector GLPG2222**

*IND opening triggers \$10 million milestone payment from AbbVie*

**Mechelen, Belgium; 1 February 2017, 22.00 CET – Galapagos NV (Euronext & NASDAQ: GLPG) announces dosing of the first patient with cystic fibrosis (CF) Class III (F508del and a gating mutation like G551D) with novel CF corrector GLPG2222 as an add-on to Kalydeco®<sup>1</sup> in a Phase 2a study. Galapagos further announced the opening of an Investigational New Drug (IND) file with the US Food & Drug Administration for GLPG2222, triggering a \$10 million milestone payment.**

The ALBATROSS Phase 2a study is a multi-center, randomized, double-blind, placebo-controlled, parallel group study to evaluate two doses of orally administered GLPG2222 in adult subjects with a diagnosis of CF harboring one F508del CFTR mutation and one gating mutation. Up to 35 evaluable subjects are planned to be included in the study. Eligible subjects must be on stable treatment with physician prescribed Kalydeco for at least 28 days at the baseline visit. They will receive one of two active doses of GLPG2222 or placebo q.d. administered for 29 days.

The primary objective of ALBATROSS is to evaluate safety and tolerability of GLPG2222 in patients. Secondary objectives will include the assessment of ppFEV<sub>1</sub>, changes of sweat chloride, and CFQ-R. Topline results are expected in Q4 2017.

“The aim of the ALBATROSS study is to enhance our understanding of GLPG2222 in a CF patient population,” said Dr. Piet Wigerinck, Chief Scientific Officer of Galapagos. “With ALBATROSS we expect to learn more about our dosing modelling for the triple combination therapy; patients who participate may potentially help other CF patients still in need of a life-changing therapy.”

The opening of the IND with the FDA forms the basis for Galapagos and AbbVie to perform future studies with GLPG2222 in the US, and triggers a \$10 million milestone payment from AbbVie to Galapagos.

### **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 \$40 million in milestone payments to date and is eligible to receive up to approximately \$580 million in total additional 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%. Galapagos has commercial rights to China and South Korea, and has an option to co-promote in Belgium, Netherlands, and Luxembourg.

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<sup>1</sup> Kalydeco® is marketed by Vertex Pharmaceuticals

## 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 any guidance given by Galapagos' management, Galapagos' strategic ambitions, the anticipated timing of clinical studies with GLPG2222 and Galapagos' other cystic fibrosis product candidates, 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 may not support registration or further development of Galapagos' product candidates 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.*