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Galapagos and AbbVie expand their cystic fibrosis collaboration

- Strong commitment from Galapagos and AbbVie to accelerate development of a triple combination therapy
- Expanded portfolio shows promise for breakthrough therapy
- Milestones increased from \$350 to \$600 million
- Patient trials expected to start in 2017

Mechelen, Belgium; 29 April 2016: Galapagos NV (Euronext & NASDAQ: GLPG) and AbbVie (NYSE: ABBV) announce that the companies have expanded their agreement in cystic fibrosis (CF) to reflect the successful expansion of their CF portfolio. Companies have agreed to increase the potential milestones to Galapagos for Phase 1 and 2 achievements, bringing the remaining total milestones in the CF alliance up to approximately \$600 million, from \$350 million. Other key collaboration terms remain in place: tiered royalty payments on net sales, ranging from mid-teens to twenty percent. Galapagos retains commercial rights to China and South Korea, and has an option to co-promote in Belgium, Netherlands, and Luxembourg.

Galapagos and AbbVie aim to develop a triple CFTR combination therapy to address 90% of patients with CF. In order to bring a more effective therapy to patients, the companies have developed multiple candidates and backups for each of the three components of a potential triple combination. 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 a statistically significant increase in chloride transport over Orkambi¹ in HBE cells with the homozygous F508del mutation. It is expected that a triple combination therapy from this collaboration will be tested in patients having the F508del mutation in 2017.

"Galapagos and AbbVie are committed to accelerate the development of a potential triple combination therapy," said Onno van de Stolpe, CEO of Galapagos. "The compounds in our CF franchise show exciting results *in vitro*, and our strong partnership with AbbVie is focused on getting these combinations into patient trials as soon as possible."

"Within a short time, AbbVie and Galapagos have been able to create an expanded portfolio of candidate CF drugs which, in combination, may offer patients new therapy options. We look forward to working rapidly with Galapagos to bring these candidate drugs through the clinic in the coming years," said Jim Sullivan, Vice President, Discovery, AbbVie.

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

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 $^{^1}$ Orkambi $^{\circ}$ 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.



financial contribution by Galapagos. Galapagos has earned \$20 million in milestone payments to date and is eligible to receive up to approximately \$600 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.

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 maturing pipeline of 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 440 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 any anticipated milestone payments or royalty payments, the anticipated timing of clinical studies, the potential activity of its candidate cystic fibrosis drugs and of a potential triple combination including these compounds for cystic fibrosis. Galapagos cautions the reader that



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forward-looking statements are not quarantees 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 Galapagos' ongoing clinical research programs in cystic fibrosis may not support registration or further development of their correctors and potentiators due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties (including the performance by AbbVie under the Galapagos-AbbVie Collaboration Agreement), and estimating the commercial potential of its 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.