Galapagos advances CF clinical development

- Initiation of Phase 1 study with corrector GLPG2222, earning Galapagos a $10 million milestone payment from AbbVie
- Expansion of CF portfolio with three novel candidate drugs, with aim to create the most effective combo

Mechelen, Belgium; 19 January 2016: Galapagos NV (Euronext & NASDAQ: GLPG) provides an update on progress made in the cystic fibrosis (CF) programs. Galapagos and AbbVie (NYSE: ABBV) 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 plan to develop multiple candidates and backups for each of the three components (1st generation correctors, next generation correctors, and potentiators) with the goal of identifying a potential triple combination. In addition to our potentiator and corrector that are being tested in the clinic, a total of four additional compounds have the potential to reach clinical development in the CF program this year.

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 chloride transport with an increase over Orkambi\(^1\) in HBE cells with the homozygous F508del mutation.

**First generation corrector series**
Dosing to humans of GLPG2222, the first 1st generation corrector in Galapagos’ portfolio, started earlier this month. This achievement earns Galapagos a $10 million milestone payment in connection with the global collaboration agreement with AbbVie. Galapagos is conducting a randomized, double-blind, placebo-controlled study over a range of doses of GLPG2222 in healthy volunteers in Belgium and expects topline results in Q2 2016. Galapagos further announces the selection of preclinical candidate GLPG2851, an additional 1st generation corrector, aiming to initiate Phase 1 with this compound by the end of 2016.

**Next-generation corrector series**
Galapagos announced selection of the first next-generation corrector GLPG2665 in October 2015, expected to enter Phase 1 by mid-2016. Today Galapagos announces selection of an additional next-generation corrector GLPG2737, expected to enter Phase 1 in healthy volunteers by Q4 2016. Galapagos and AbbVie are also developing an alternative series of next-generation correctors with different activity and expect to nominate candidates and additional compounds from that series later in 2016.

**Potentiator series**
Galapagos has made regulatory filings for exploratory Phase 2 studies in CF patients for potentiator GLPG1837, and has received the first approvals to start from a number of countries. This early

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\(^1\) Orkambi\(^\circledast\) 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.
exploratory Phase 2 program with GLPG1837 will be conducted in Europe in G551D and S1251N mutation types. Additional potentiator GLPG2451 has entered preclinical development and is expected to move into Phase 1 trials in Q2 2016.

“Galapagos and AbbVie continue to make strong progress with our cystic fibrosis portfolio,” said Onno van de Stolpe, CEO of Galapagos. “The CF franchise has really expanded into a full-sized portfolio. The resulting breadth, depth, and preclinical promise of this collection of modulators brings us again closer to our aim of bringing a superior triple combination therapy to CF patients.”

About the Galapagos – AbbVie collaboration in cystic fibrosis
In September 2013 Galapagos and AbbVie, a global biopharmaceutical company, 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 $20 million in milestone payments to date and is eligible to receive up to $340 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%.

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 mucus 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 three Phase 2, four Phase 1, four pre-clinical, and 20 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 400 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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Galapagos forward-looking statements
This release may contain forward-looking statements, including statements regarding any anticipated milestone payment, the anticipated timing of clinical studies, the potential activity of GLPG 2222, GLPG2665, GLPG 2737, GLPG 2851, GLPG1837, GLPG2451 and of a potential triple combination including these compounds for cystic fibrosis. 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 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 our product candidates. A further list and description of these risks, uncertainties and other risks can be found in the company’s Securities and Exchange Commission filing and reports, including in the company’s prospectus filed with the Securities and Exchange Commission on May 14, 2015 and subsequent filings and reports filed by the company with the Securities and Exchange Commission. 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.