Galapagos advances triple combination therapy in cystic fibrosis

- GLPG2665, a next-generation (C2) corrector, together with the other two components of the triple combination, show up to six-fold greater chloride transport than Orkambi® \textit{in vitro}
- Triple combination therapy of C2 with GLPG2222 and GLPG1837 expected to address 80% of mutations in the CF population
- Multiple series of C2 correctors identified, each with unique mode of action
- GLPG2665 enters pre-clinical development and completes the first Galapagos-AbbVie triple combination therapy

Mechelen, Belgium; 15 October 2015: Galapagos NV (Euronext & NASDAQ: GLPG) announced today that GLPG2665 has been selected as the first next generation corrector compound candidate. Galapagos discovered multiple C2 corrector compound series, each with a different chemical scaffold and corresponding unique and complementary mode of action. GLPG2665 is the first candidate to complete the potential triple combination therapy for the delta F508 (class II) mutation in cystic fibrosis. GLPG2665 will now enter pre-clinical development, and is expected to enter Phase 1 studies by mid 2016. GLPG2665 in combination with corrector GLPG2222 and potentiator GLPG1837 consistently have shown restoration of healthy activity level in human bronchial epithelial (HBE) cells of patients with the Class II F508del mutation. The combination resulted in chloride transport up to six-fold greater than Orkambi in HBE cells with the homozygous F508del mutation. Poor functioning of the CFTR channel is the major deficit in patients with cystic fibrosis.

“This is a critical step in the development of our cystic fibrosis portfolio,” said Onno van de Stolpe, CEO of Galapagos. “The collaboration with AbbVie delivered novel corrector GLPG2665, the first of multiple correctors to complement our triple combination therapy. The race to bring a truly disease-modifying therapy to the vast majority of patients with CF has started, which is good news for the patients. Galapagos is fully committed to advancing our combination therapy GLPG1837, GLPG2222, and GLPG2665 as rapidly as possible.”

Advancement of the third component of the triple combination therapy into development brings the Galapagos-AbbVie collaboration closer to its goal of bringing disease-modifying therapies to CF patients. Galapagos expects to enter Phase 2 studies with potentiator GLPG1837 in Class III mutation patients and a Phase 1 study with corrector GLPG2222 in healthy volunteers by filing before year-end.

About the Galapagos – AbbVie collaboration in cystic fibrosis

In September 2013 Galapagos signed an agreement with AbbVie in which they will work collaboratively to develop and commercialize oral drugs that address the main mutations in CF patients, including F508del and G551D. 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 II, AbbVie will be responsible for Phase III,

1) Orkambi® 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 \textit{F508del} mutation (\textit{F508del}/\textit{F508del}) in their \textit{CFTR} gene.
with financial contribution by Galapagos. Galapagos achieved a $10 million milestone in 2014 and is eligible to receive up to $350 million in total additional payments for developmental and regulatory milestones, sales milestones upon the achievement of minimum annual net sales thresholds and additional 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 27. 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, with a pipeline comprising three Phase 2 programs, two Phase 1 trials, five pre-clinical studies, and 20 discovery small-molecule and antibody programs in cystic fibrosis, inflammation, and other indications. Filgotinib is an orally-available, selective inhibitor of JAK1 for the treatment of rheumatoid arthritis and potentially other inflammatory diseases. Galapagos has reported good activity and a favorable safety profile in both the DARWIN 1 and 2 trials in RA. Galapagos is preparing to enter Phase 3 studies in RA and to report Phase 2 topline results with filgotinib in Phase 2 in Crohn’s disease. In the field of cystic fibrosis, AbbVie and Galapagos collaborate to develop and commercialize molecules that address mutations in the CFTR gene. Potentiator GLPG1837 has completed a Phase 1 trial, corrector GLPG2222 is expected to enter Phase 1 by end 2015, and C2 corrector GLPG2665 is expected to enter Phase 1 by mid 2016. GLPG1205, a first-in-class inhibitor of GPR84 and fully-owned by Galapagos, will report topline results in Q4 2015 from a Phase 2 proof-of-concept trial in ulcerative colitis patients. GLPG1690, a fully proprietary, first-in-class inhibitor of autotaxin, has shown favorable safety in a Phase 1 trial and is expected to enter Phase 2 in idiopathic pulmonary fibrosis. 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 info at www.glpg.com

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Galapagos forward-looking statements
This release may contain forward-looking statements, including statements regarding the anticipated timing of clinical studies, the potential activity of GLPG2665 and of a potential triple combination including this compound 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 filgotinib due to safety, efficacy or other reasons), Galapagos’ reliance on collaborations with third parties (including its collaboration partner, AbbVie, who may not devote sufficient resources to the development and commercialization of the cystic fibrosis programs), 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 future 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.