Regulated information 16 February 2015, 22.00 CET

Galapagos starts SAPHIRA Phase 2 study with GLPG1837 in cystic fibrosis patients

Topline results in Class III mutation patients expected Q4 2016

Mechelen, Belgium; 16 February 2016 – Galapagos NV (Euronext & NASDAQ: GLPG) announced today the first dosing in its Phase 2 exploratory program of GLPG1837 in patients with cystic fibrosis (CF).

GLPG1837 is a candidate CFTR potentiator drug in clinical development for the treatment of Class III mutations in cystic fibrosis. The SAPHIRA Phase 2 program will explore the safety, tolerability and efficacy properties of GLP1837 in CF patients with a G551D (SAPHIRA 1) or S1251N (SAPHIRA 2) Class III mutation. Topline results from the SAPHIRA Phase 2 program are expected in Q4 2016.

"Today's announcement is a landmark achievement in our CF program, with the first CF patient being treated with a Galapagos potentiator," said Onno van de Stolpe, CEO of Galapagos. "Recruitment for the SAPHIRA program is rapid, and we look forward to seeing to what extent our promising *in vitro* data translates into clinical results. We aim to start and report a number of clinical studies with additional compounds in the CF portfolio throughout 2016."

Details of the SAPHIRA Phase 2 program

SAPHIRA 2, an open-label study of two doses of GLPG1837 in at least six CF patients with the S1251N mutation, was first dosed in a patient last week. SAPHIRA 1, an open-label study of three doses of GLPG1837 in at least 12 patients with the G551D mutation, is expected to begin dosing soon. The SAPHIRA Phase 2 program will explore the safety, tolerability, efficacy, and medicine-like properties of GLPG1837 in patients in six EU countries and Australia. Primary objectives are to evaluate the safety and tolerability; secondary objectives are to assess changes in sweat chloride from baseline as the biomarker of cystic fibrosis transmembrane conductance regulator (CFTR) ion channel function and to explore the changes in pulmonary function (forced expiratory volume in 1 second [FEV1]) from baseline. Both studies will include subjects treated with Kalydeco®[1] as well as those who are naïve to this drug. In each study, different doses of GLPG1837 tablets will be administered twice daily for a total duration of four weeks.

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 in a potential triple combination therapy 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

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[1] Kalydeco® is a prescription medicine sold by Vertex Pharmaceuticals, used for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have several specific Class III mutations in the CFTR protein including G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, or R117H.

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 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 three Phase 2, two 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 the anticipated timing of clinical studies, the potential activity and clinical utility of potentiator GLPG1837 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 GLPG1837 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.