

Servier and Galapagos announce start of global ROCCELLA Phase 2 clinical trial with S201086/GLPG1972 in osteoarthritis patients

Paris (France) and Mechelen (Belgium), 26 June 2018, 22.01 CET – Servier, an independent international pharmaceutical company, and Galapagos NV (Euronext & NASDAQ: GLPG) announce the start of a global Phase 2 trial with S201086/GLPG1972 in knee osteoarthritis patients: ROCCELLA. Galapagos will be eligible to receive a €9 million milestone payment upon first dosing of a patient in ROCCELLA.

Servier and Galapagos have submitted and will further submit clinical trial applications in a number of countries in North and South America, Europe and Asia. The study will now be initiated in the US and Hungary with other countries expected to follow, pending the respective regulatory approvals. ROCCELLA will be a multiregional, randomized, double-blind, placebo-controlled, dose ranging trial evaluating the efficacy and safety of three different once-daily doses of S201086/GLPG1972 in patients with knee osteoarthritis (OA). ROCCELLA is planned to recruit approximately 850 patients in up to 15 countries. Galapagos will be responsible for ROCCELLA in the United States, where 300 patients are targeted to be recruited. Servier will run the trial in all other countries.

The primary objective of ROCCELLA is to demonstrate the efficacy of at least one dose of S201086/GLPG1972 compared to placebo in reducing cartilage loss after 52 weeks of treatment. Cartilage thickness will be measured using quantitative magnetic resonance imaging of the central medial tibiofemoral compartment of the target knee. Secondary objectives include safety and tolerability, several additional measures of structural progression, changes in bone area, pain, function, stiffness, and patient global assessment.

S201086/GLPG1972 is a disease-modifying osteoarthritis drug (DMOAD) candidate targeting efficiently a cartilage degrading enzyme called ADAMTS-5, as confirmed in two animal models. A Phase 1 trial in healthy volunteers met all its safety and pharmacokinetic targets and also demonstrated that S201086/GLPG1972 reduced by approximately 50% within two weeks the blood level of ARGS neopeptide, a biomarker for cartilage breakdown. In a more recent Phase 1b trial in OA patients in the United States, similar findings were seen over a four-week period. Specifically, S201086/GLPG1972 was well tolerated and it reduced, in a dose-dependent manner, the ARGS neopeptide blood levels by up to 50%.

"People living with osteoarthritis of the knee experience a major loss of quality of life, mainly because of the ever-present pain and increasing loss of mobility. Any therapeutic innovation that can prevent or slow down the underlying cartilage loss will thus address a huge unmet patient need for the many people affected by osteoarthritis in our aging populations", said Lode Dewulf, Chief Patient Officer at Servier.

"The robust design of ROCCELLA should provide deep insights into the disease-modifying potential and the safety and tolerability of this novel therapeutic candidate in patients with knee OA. We have seen clear target engagement in OA patients; now we should be able to answer how this translates to protection against cartilage breakdown," said Dr. Walid Abi-Saab, Chief Medical Officer of Galapagos. "We look forward to working with our collaboration partner Servier to execute ROCCELLA as rapidly as possible, with the goal of providing OA patients with a first disease-modifying drug."

"Due to its unique mechanism of action based on the inhibition of cartilage degradation, S201086/GLPG1972 has the potential to help patients with osteoarthritis by altering the course of their disease. We look forward to launch the ROCCELLA Phase 2 trial as a global effort conducted jointly by Servier and Galapagos to fulfill the needs of patients suffering from osteoarthritis", said Philippe Moingeon Head of Center for Therapeutic Innovation at Servier.

OA is a highly prevalent and disabling pathology. So far, no treatment is available to counteract disease progression, and patients are left with only symptomatic treatments. As a result, OA represents an important unmet medical need. Galapagos developed investigational molecule S201086/GLPG1972 with the potential of becoming a first-in-class DMOAD as part of a collaboration with Servier signed in 2010. Galapagos has full U.S. commercial rights to S201086/GLPG1972. Under the terms of the agreement, Galapagos is also eligible to receive development, regulatory and other milestone payments plus royalties upon commercialization outside the United States.

S201086/GLPG1972 is an investigational drug candidate and its safety and efficacy have not yet been established.


About Servier

Servier is an international pharmaceutical company governed by a non-profit foundation, with its headquarters in France (Suresnes). With a strong international presence in 148 countries and a turnover of 4.152 billion euros in 2017, Servier employs 21,600 people worldwide. Entirely independent, the Group reinvests 25% of its turnover (excluding generic drugs) in research and development and uses all its profits for development. Corporate growth is driven by Servier's constant search for innovation in five areas of excellence: cardiovascular, immune-inflammatory and neuropsychiatric diseases, cancers and diabetes, as well as by its activities in high-quality generic drugs. Servier also offers eHealth solutions beyond drug development.

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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. Galapagos' pipeline comprises Phase 3 through to discovery programs in cystic fibrosis, inflammation, fibrosis, osteoarthritis and other indications. Our target discovery platform has delivered three novel mechanisms showing promising patient results in, respectively, inflammatory diseases, idiopathic pulmonary fibrosis and atopic dermatitis. 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 640 employees, operating from its Mechelen, Belgium headquarters and facilities in the Netherlands, France, Switzerland, the US and Croatia. More information at www.glpg.com.

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Galapagos forward-looking statements

This release may contain forward-looking statements, including, among other things, statements regarding the mechanism of action and profile of, and timing and results of clinical trials with, and potential commercialization of, GLPG1972. 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 that Galapagos' expectations regarding its GLPG1972 development program may be incorrect, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from the ongoing clinical research programs may not support registration or further development of GLPG1972 due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties (including its collaboration partner for OA Servier), 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 other 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.