

Servier and Galapagos complete enrollment of global ROCCELLA Phase 2 clinical trial with GLPG1972/S201086 in knee osteoarthritis patients

Mechelen, Belgium and Paris, France, 11 JUNE 2019, 07.00 CET – Servier and Galapagos NV (Euronext & NASDAQ: GLPG) completed recruitment for their ROCCELLA Phase 2 trial with GLPG1972/S201086, ahead of schedule.

ROCCELLA is a multi-regional, randomized, double-blind, placebo-controlled, dose ranging trial evaluating the efficacy and safety of three different once-daily oral doses of GLPG1972/S201086 in patients with knee osteoarthritis (OA). ROCCELLA includes more than 850 patients in 12 countries in Europe, Asia, North and South America. Galapagos is responsible for ROCCELLA in the United States, where more than 300 patients were recruited. Servier is responsible for this trial in all other countries, where the rest of the patients were recruited.

The primary objective of ROCCELLA is to evaluate the efficacy of at least one dose of GLPG1972/S201086 compared to placebo in reducing knee OA progression after 52 weeks of treatment. This will be assessed by measuring cartilage thickness with MRI. Secondary objectives include safety and tolerability, several additional measures of structural progression, pain, function, stiffness, and patient global assessment.

“We are thrilled with the willingness of OA clinical centers and patients worldwide to participate in ROCCELLA,” said Dr Walid Abi-Saab, Chief Medical Officer of Galapagos. *“We look forward to learning about the trial results next year. The OA community eagerly awaits clinical evidence of a disease-modifying candidate in this disease with substantial unmet medical need.”*

“The completion of the overall recruitment in nine months reflects the high interest expressed by patients for GLPG1972/S201086,” said Philippe Moingeon, Head of Center for Therapeutic Innovation Immuno-Inflammatory Disease at Servier. *“We are pleased that the constructive collaboration established between Servier and Galapagos allows us both to streamline efficiently the development of this orally administered drug candidate, potentially to the ultimate benefit of patients with knee OA.”*

GLPG1972/S201086 is a disease-modifying osteoarthritis drug (DMOAD) candidate that, in two animal models, has been shown to efficiently target a cartilage degrading enzyme called ADAMTS-5. A Phase 1 study in healthy subjects met all of its safety and pharmacokinetic targets and also demonstrated that GLPG1972/S201086 reduced the blood level of the ARGS neo-epitope by approximately 50% within two weeks. ARGS is a biomarker for ADAMTS-5 activity and, as such, increased levels of ARGS reflect increased 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, GLPG1972/S201086 was well tolerated and reduced ARGS blood levels up to 50%.

OA is a highly prevalent and disabling pathology. There are no treatments available today that counteract disease progression. Patients are left with only symptomatic treatments. As a result, OA represents an important unmet medical need. Galapagos developed investigational molecule GLPG1972/S201086 with the potential of becoming a first-in-class DMOAD as part of a collaboration with Servier that began in 2010. Galapagos has full U.S. commercial rights to GLPG1972/S201086 and is eligible to receive development, regulatory and other milestone payments plus royalties from Servier upon commercialization outside the United States, if approved. Galapagos has received Fast Track designation for osteoarthritis from the US FDA for GLPG1972/S201086.

GLPG1972/S201086 is an investigational drug candidate and its safety and efficacy have not yet been established. More information on the ROCCELLA trial can be found at www.clinicaltrials.gov (NCT03595618) and www.clinicaltrialsregister.eu.

About Galapagos

Galapagos (Euronext & NASDAQ: GLPG) discovers and develops small molecule medicines with novel modes of action, three of which show promising patient results and are currently in late-stage development in multiple diseases. Our pipeline comprises Phase 3 through to discovery programs in inflammation, fibrosis, osteoarthritis and other indications. Our ambition is to become a leading global biopharmaceutical company focused on the discovery, development and commercialization of innovative medicines. More information at www.glp.com.

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 149 countries and a turnover of 4.2 billion euros in 2018, Servier employs 22,000 people worldwide. Entirely independent, the Group reinvests 25% of its turnover (excluding generics) 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 neurodegenerative diseases, oncology and diabetes, as well as by its activities in high-quality generic drugs. Servier also offers eHealth solutions beyond drug development. One hundred million patients are treated daily worldwide with Servier drugs. More information: www.servier.com

Follow us on Social Media:



Contacts

Investor contacts Galapagos:

Elizabeth Goodwin
VP IR
+1 781 460 1784

Sofie Van Gijssel
Director IR
+32 485 19 14 15
ir@glpg.com

Media contacts Galapagos:

Carmen Vroonen
Senior Director Communications & Public Affairs
+32 473 82 48 74

Evelyn Fox
Director Communications
+31 6 53 591 999
communications@glpg.com

Servier Press contacts:

Sonia Marques: sonia.marques@servier.com – Tel. +33 (0)1 55 72 40 21 / + 33 (0) 7 84 28 76 13
Jean-Clément Vergeau: jean-clement.vergeau@servier.com – Tel. +33 (0)1 55 72 46 16 / + 33 (0) 6 79 56 75 96
Karine Bousseau: karine.bousseau@servier.com – Tel. +33 (0)1 55 72 60 37 / + 33 (0) 6 49 92 16 05

Galapagos forward-looking statements

This release may contain forward-looking statements, including, among other things, statements regarding the mechanism of action and profile of, 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 GLPG1972. 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.