

Galapagos and Servier report topline results for ROCCELLA Phase 2 clinical trial with GLPG1972/S201086 in knee osteoarthritis patients

Mechelen, Belgium and Paris, France, October 15, 2020, 22.01 CET; regulated information – Servier and Galapagos NV (Euronext & NASDAQ: GLPG) report that no signal of activity was observed in the topline results in their ROCCELLA Phase 2 trial with GLPG1972/S201086.

ROCCELLA is a global, double-blind, placebo-controlled, dose ranging trial evaluating the efficacy and safety of three different once-daily oral doses of GLPG1972/S201086 in 932 patients with knee osteoarthritis (OA) over 52 weeks of treatment. The study population was aged between 40 to 76 years (mean age was 63), mainly female (70%) and with a mean disease duration of 7 years.

The primary objective of ROCCELLA was to demonstrate the efficacy of at least one dose of GLPG1972/S201086 compared to placebo after 52 weeks of treatment in reducing cartilage loss of the central medial tibiofemoral compartment of the target knee via quantitative MRI.

The trial failed to meet the primary objective. The change from baseline to week 52 in cartilage thickness, in mm (SD) was -0.116 (0.27) for the placebo group and -0.068 (0.20), -0.097 (0.27) and -0.085 (0.22), for the low, medium and high dose, respectively. Statistically significant difference versus placebo was not reached in any of the treated groups.

There was no significant difference compared to placebo observed on secondary endpoints, including clinical outcomes.

Additional analyses are being conducted to fully evaluate the results, which will be presented at upcoming medical conferences.

GLPG1972/S201086 was generally well-tolerated by patients in this Phase 2 trial.

“While we are disappointed that ADAMTS-5 inhibition by GLPG1972/S201086 proved not to make a difference in this trial, we want to express our gratitude to all participating patients and investigators. This study result, while not what we hoped for, does add to the body of knowledge to help fight OA, a disease with substantial unmet medical need,” said Dr Walid Abi-Saab, Chief Medical Officer of Galapagos.

“We are pleased to have performed this study with Galapagos. Unfortunately, the ROCCELLA results provided insufficient evidence of GLPG1972/S201086 efficacy in patients with knee osteoarthritis. We acknowledge the importance of assessing this innovative mechanism of action in the clinical setting and we will continue analyzing the data for better knowledge of the disease for the benefit of the patients and for future developments. We would like also to thank all patients and investigators for



participating in this very important study,” said Dr Patricia Belissa-Mathiot, Director of Clinical Development and R&D Chief Medical Officer at Servier.

About the ROCCELLA trial

ROCCELLA was 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. ROCCELLA included 932 patients in 12 countries in Europe, Asia, North and South America. Galapagos was responsible for ROCCELLA in the United States, where 326 patients were recruited. Servier was responsible for this trial in 11 countries, where 606 patients were recruited.

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 150 countries and a total revenue of 4.6 billion euros in 2019, Servier employs 22,000 people worldwide. Entirely independent, the Group invests on average 25% of its total revenue (excluding generics) every year in research and development and uses all its profits for its development. Corporate growth is driven by Servier's constant commitment in five areas of excellence: cardiovascular, immune-inflammatory, and neurodegenerative diseases, cancer and diabetes, as well as by its activities in high-quality generic drugs. Servier also offers eHealth solutions beyond drug development.

More information: www.servier.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, 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.

This press release contains inside information within the meaning of Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (market abuse regulation).