

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

Mechelen, Belgium and Paris, France, 15 OCTOBER 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, several of which show promising patient results and are currently in late-stage development in multiple diseases. Our pipeline comprises discovery through Phase 3 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.glpq.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, oncology 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 press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, that are subject to risks, uncertainties and other factors that could cause actual results to differ materially from those referred to in the forward-looking statements and, therefore, the reader should not place undue reliance on them. These risks, uncertainties and other factors include, without limitation, the risk that ongoing and future clinical studies with GLPG1972/S201086 may not be completed in the currently envisaged timelines or at all, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from the ongoing and planned clinical research programs may not support registration or further development of GLPG1972/S201086 due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties (including our collaboration partner for GLPG1972/S201086, Servier) and that Galapagos' estimations regarding its GLPG1972/S201086 development program and regarding the commercial potential of GLPG1972/S201086, may be incorrect, as well as those risks and uncertainties identified in our Annual Report on Form 20-F for the year ended 31 December 2019 and our subsequent filings with the SEC. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The forward-looking statements contained herein are based on management's current expectations and beliefs and speak only as of the date hereof, and Galapagos makes no commitment to update or publicly release any revisions to forward-looking statements in order to reflect new information or subsequent events, circumstances or changes in expectations.



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).