

## **Galapagos receives Fast Track designation from FDA for GLPG1972/S201086 in osteoarthritis**

**Mechelen, Belgium; 27 November 2018, 22.01 CET – Galapagos NV (Euronext & NASDAQ: GLPG) announced today that the FDA has granted GLPG1972/S201086 Fast Track designation for the treatment of patients with osteoarthritis (OA).**

The US Food and Drug Administration's (FDA's) Fast Track program is designed to facilitate the development and expedite the review of drugs that treat serious or life-threatening diseases or conditions and that demonstrate the potential to address unmet medical needs. Drugs that receive this designation are eligible for more frequent interactions with the FDA and are potentially eligible for priority review and rolling review of a New Drug Application (NDA). The purpose of this FDA program is to get important new drugs to patients earlier.

Galapagos is developing investigational molecule GLPG1972/S201086 with the potential to become a first-in-class disease-modifying osteoarthritis drug (DMOAD) as part of a collaboration with Servier<sup>1</sup> signed in 2010. Galapagos has full US commercial rights to GLPG1972/S201086, with Servier retaining the ex-US rights. Under the terms of the agreement, Galapagos is also eligible to receive development, regulatory and other milestone payments plus royalties upon commercialization outside the US. In June 2018, Galapagos and Servier announced the start of the global 52-week ROCCELLA Phase 2 trial with GLPG1972/S201086 in knee osteoarthritis patients.

"The Fast Track designation by the FDA is a recognition of the high unmet medical need in OA, and the potential of GLPG1972/S201086 as a new treatment option," said Dr. Walid Abi-Saab, CMO of Galapagos. "Together with our collaboration partner Servier, we look forward to accelerating the development of GLPG1972/S201086 as a potential first disease-modifying osteoarthritis drug."

### **About GLPG1972/S201086**

GLPG1972/S201086 is a DMOAD candidate targeting 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 within two weeks, GLPG1972/S201086 reduced the blood level of ARGS neopeptide, a biomarker for cartilage breakdown, by approximately 50%. In a more recent Phase 1b trial in osteoarthritis patients in the United States, similar findings were seen over a four-week period. Specifically, GLPG1972/S201086 was well tolerated and it reduced, in a dose-dependent manner, the ARGS neopeptide blood levels by up to 50%.

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

For more information about GLPG1972/S201086: [www.glpg.com/glpg-1972](http://www.glpg.com/glpg-1972).

### **About the ROCCELLA trial**

ROCCELLA is a multiregional, 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 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 intended to be recruited. Servier will run the trial in all other countries.

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<sup>1</sup> Servier is an international pharmaceutical company governed by a non-profit foundation, with headquarters in France (Suresnes).

The primary objective of ROCCELLA is to evaluate the efficacy of at least one dose of GLPG1972/S201086 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.

For information about the study with GLPG1972/S201086: [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT03595618).

### **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 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. Our ambition is to become a leading global biopharmaceutical company, focused on the development and commercialization of innovative medicines that will improve people's lives. The Galapagos group, including fee-for-service subsidiary Fidelta, has approximately 700 employees, operating from its Mechelen, Belgium headquarters and facilities in the Netherlands, France, Switzerland, the US and Croatia. More information at [www.glpg.com](http://www.glpg.com).

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#### **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/S201086, as well as interactions with regulators in this framework. 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/S201086 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 further development of GLPG1972/S201086 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.*