Galapagos reports initiation of global ROCCELLA Phase 2 clinical trial with GLPG1972/S201086 in osteoarthritis patients

Mechelen, Belgium, September 24 2018, 07.30 CET – Galapagos NV (Euronext & NASDAQ: GLPG) reports first dosing in the global ROCCELLA Phase 2 trial with GLPG1972/S201086 in knee osteoarthritis patients. Galapagos receives a €9 million milestone payment from its collaboration partner Servier for this achievement.

ROCCELLA is a multiregional, randomized, double-blind, placebo-controlled, dose ranging trial evaluating the efficacy and safety of three different once-daily doses of GLPG1972/S201086 in patients with knee osteoarthritis (OA). ROCCELLA is planned to recruit approximately 850 patients in countries in Europe, Asia, North America and South America. Galapagos is 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 GLPG1972/S201086 compared to placebo in reducing cartilage loss after 52 weeks of treatment. This cartilage loss will be measured precisely by magnetic resonance imaging (MRI). Secondary objectives include safety and tolerability, several additional measures of structural progression, improvement in pain, function, stiffness, and patient global assessment.

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 trial in healthy volunteers met all of its safety and pharmacokinetic targets and also demonstrated that GLPG1972/S201086 reduced the blood level of the ARGS neopeptipe by approximately 50% within two weeks. ARGS neopeptipe is a biomarker for ADAMTS-5 activity and, as such, serves as a reflection of 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 neopeptipe blood levels by 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.

GLPG1972/S201086 is an investigational drug candidate and its safety and efficacy have not yet been established. More information on the clinical study can be found at 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 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 675 employees, operating from its Mechelen,

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Galapagos forward-looking statements
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