

Gilead submits new drug application to U.S. Food and Drug Administration under priority review for filgotinib for rheumatoid arthritis treatment

Foster City, Calif., and Mechelen, Belgium; 19 December 2019, 22.30 CET – Galapagos NV (Euronext & NASDAQ: GLPG) today announced that its collaboration partner, Gilead Sciences, Inc. (NASDAQ: GILD) has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for filgotinib, an investigational, oral, selective JAK1 inhibitor for the treatment of adults who are living with moderate-to-severe rheumatoid arthritis (RA). A priority review voucher was submitted with the NDA, shortening the anticipated time for review.

The NDA filing is supported by 52-week data from the global Phase 3 FINCH clinical program, which evaluated the efficacy and safety of filgotinib in 3,452 patients with moderate to severely active RA. In the FINCH studies, filgotinib met its primary endpoints and demonstrated durable efficacy and safety results across multiple RA patient populations, including in people with prior inadequate response to methotrexate treatment (MTX), those who were intolerant to one or more biologic treatments and those who were MTX treatment-naïve. Safety results were consistent across the trials and further reinforce the long-term safety and tolerability profile of filgotinib for a broad range of RA patients.

As part of the collaboration terms, upon NDA submission, Galapagos receives a \$20 million milestone payment from Gilead.

This NDA is the third regulatory agency submission for filgotinib in the past 5 months following submissions to the European Medicines Agency and Japanese Ministry of Health, Labor and Welfare earlier this year.

Despite the availability of current therapies, people living with RA may face persistent disease symptoms and inadequate responses to currently available therapies. One in five patients do not achieve complete disease remission during their lifetimes and remain in need of treatment options.

“The new drug application submission for filgotinib represents an important step forward in bringing a potential new treatment option to people living with RA,” said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. “In clinical trials, filgotinib has demonstrated an efficacy and tolerability profile that may offer meaningful improvements in RA treatment response for patients with this chronic, debilitating disease.”

“Following submission for approval of filgotinib in RA with the European and Japanese authorities, today’s announcement marks another key step in Galapagos’ history: a first ever NDA submission for one of our programs,” said Dr. Walid Abi-Saab, Chief Medical Officer at Galapagos. “We are excited about the progress made, and look forward to hopefully bringing filgotinib to patients suffering from RA across these territories.”

Filgotinib is an investigational agent and is not approved by any regulatory authority. Its efficacy and safety have not been established.

About the filgotinib collaboration¹

Gilead and Galapagos are collaborative partners in the global development and commercialization of filgotinib in RA, and other potential inflammatory indications. In the U.S., Gilead is solely responsible for the commercialization of filgotinib, pending approval of filgotinib by the FDA, and Galapagos is eligible for further milestones as well as royalties of 20-30% on filgotinib sales in this

territory. If approved, Gilead and Galapagos will co-commercialize filgotinib in a number of European territories.

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. Galapagos' pipeline comprises Phase 3 through to discovery programs in inflammation, fibrosis, osteoarthritis and other indications. The Company's ambition is to become a leading global biopharmaceutical company focused on the discovery, development and commercialization of innovative medicines. More information at www.glpg.com.

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California. For more information on Gilead Sciences, please visit the company's website at www.gilead.com.

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Forward-looking statements

This release may contain forward-looking statements with respect to Galapagos, including statements regarding Galapagos' strategic ambitions, the success of Galapagos' filgotinib collaboration, the mechanism of action and potential safety and efficacy of filgotinib, the progression and results of clinical studies with filgotinib, the regulatory pathway for filgotinib and the timing of regulatory filings. 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 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 filgotinib due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties (including its collaboration partner for filgotinib, Gilead), and estimating the commercial potential of filgotinib. 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 subsequent 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.

ⁱ Gilead & Galapagos filgotinib clinical program trial details: SELECTION ([NCT02914522](#)); DIVERSITY ([NCT02914561](#)); PENGUIN 1 ([NCT04115748](#)); PENGUIN 2 ([NCT04115839](#))