

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of December 2019

Commission File Number: 001-37384

GALAPAGOS NV
(Translation of registrant's name into English)

Generaal De Wittelaan L11 A3
2800 Mechelen, Belgium
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F [X] Form 40-F []

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

The information contained in this Report on Form 6-K, including Exhibit 99.1, except for the quote of Dr. Merdad Parsey and the quote of Dr. Walid Abi-Saab contained in Exhibit 99.1, is hereby incorporated by reference into the Company's Registration Statements on Forms F-3 (File No. 333-230639) and S-8 (File Nos. 333-204567, 333-208697, 333-211834, 333-215783, 333-218160, 333-225263 and 333-231765).

On December 19, 2019, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

(c) [Exhibit 99.1](#). Press release dated December 19, 2019

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GALAPAGOS NV
(Registrant)

Date: December 19, 2019

/s/ Xavier Maes
Xavier Maes
Company Secretary

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 collaborationⁱ

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.glp.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.

Contact

Investors:

Elizabeth Goodwin

VP Investor Relations
+1 781 460 1784

Sofie Van Gijssel
Director Investor Relations
+32 485 19 14 15
ir@glpg.com

Media:

Carmen Vroonen
Senior Director Communications & Public Affairs
+32 473 824 874

Evelyn Fox
Director Communications
+31 6 53 591 999
communications@glpg.com

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](#))