# 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 August 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 the exhibits but excluding the quotes of John Sundy and 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 August 15, 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 August 15, 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: September 5, 2019

/s/ Xavier Maes
Xavier Maes
Company Secretary

# EUROPEAN MEDICINES AGENCY VALIDATES MARKETING APPLICATION FOR FILGOTINIB FOR THE TREATMENT OF RHEUMATOID ARTHRITIS

**Foster City, Calif. and Mechelen, Belgium – August 15, 2019 22.01 CET –** Gilead Sciences, Inc. (NASDAQ: GILD) and Galapagos NV (Euronext & NASDAQ: GLPG) today announced that the Marketing Authorization Application (MAA) for filgotinib, an investigational, oral, selective JAK1 inhibitor, for the treatment of adults with rheumatoid arthritis (RA) has been validated and is now under evaluation by the European Medicines Agency (EMA).

"We are excited about the validation of this application which is an important milestone in our ongoing work to improve the lives of people living with rheumatoid arthritis and other inflammatory conditions," said John Sundy, MD, PhD, Senior Vice President, Inflammation and Respiratory Diseases, Gilead Sciences.

The MAA for filgotinib is supported by 24-week data from the Phase 3 FINCH clinical trials in which once-daily treatment with filgotinib achieved improvements in clinical signs and symptoms, achievement of low disease activity and remission, and inhibition of structural damage for different sub-populations of patients living with RA. Across the FINCH program, safety data were consistent with previously reported results.

"We are very happy with the validation of the filgotinib MAA by the EMA, as this represents the latest step forward in our partnership with Gilead to bring filgotinib as a new treatment option to RA patients across Europe," said Dr. Walid Abi-Saab, Chief Medical Officer at Galapagos.

The filgotinib filing will be reviewed by the EMA under the centralized licensing procedure for all 28 member states of the European Union, as well as Norway, Iceland, and Liechtenstein. In early July, Gilead announced plans to submit a New Drug Application (NDA) for filgotinib for the treatment of RA in the United States before the end of the year.

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

## About the Galapagos - Gilead Collaboration

Galapagos and Gilead entered into a global collaboration for the development and commercialization of filgotinib in inflammatory indications. The FINCH studies are among several clinical trials of filgotinib in inflammatory diseases, including the EQUATOR Phase 2 study in psoriatic arthritis, the TORTUGA Phase 2 study in ankylosing spondylitis, the DIVERSITY Phase 3 trial in Crohn's disease (also small bowel and fistulizing Crohn's disease Phase 2 studies) and the Phase 3 SELECTION trial in ulcerative colitis.

#### **About Galapagos**

Galapagos (Euronext & NASDAQ: GLPG) discovers and develops small molecule medicines with novel modes of action, three of which show patient results and are currently in late-stage development in multiple diseases. Its pipeline comprises Phase 3 through to discovery programs in inflammation, fibrosis, osteoarthritis and other indications. Galapagos' 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.

#### **Galapagos Contacts**

# **Investors:**

Elizabeth Goodwin VP IR +1 781 460 1784

Sofie Van Gijsel Director IR +32 485 19 14 15 ir@glpg.com

#### Media:

Carmen Vroonen Senior Director Communications +32473824874

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

#### **Gilead Contacts**

Investors: Media:

Sung Lee, Investors +1 (650) 524-7792

Arran Attridge, Media +1 (650) 425-8975

### **Galapagos Forward-Looking Statements**

This release may contain forward-looking statements with respect to Galapagos, including statements regarding Galapagos' strategic ambitions, 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.

#### **Gilead Forward-Looking Statement**

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the risk that EMA, the European Commission and other regulatory agencies may not approve filgotinib for the treatment of RA, and any marketing approvals, if granted, may have significant limitations on its use. As a result, filgotinib may never be successfully commercialized. There is also the possibility that Gilead may be unable to file an NDA for filgotinib in the United States in the currently anticipated timelines. Further, there is the possibility of unfavorable results from ongoing and additional clinical trials involving filgotinib. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.