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 October 2022

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, is hereby incorporated by reference into the Company's Registration Statements on Form S-8 (File Nos. 333-204567, 333-208697, 333-211834, 333-215783, 333-218160, 333-225263, 333-231765, 333-249416 and 333-260500).

On October 3, 2022, 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 October 3, 2022

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: October 3, 2022

/s/ Annelies Denecker
Annelies Denecker
Company Secretary

EXHIBIT 99.1

Galapagos receives positive CHMP opinion for Jyseleca® European label update based on testicular function safety data from MANTA/RAy studies

Type II variation[1] regulatory application to amend the European label of Jyseleca® (filgotinib) based on data from MANTA and MANTA-RAy studies in patients with inflammatory bowel disease (IBD) and rheumatic conditions (RC) respectively

Mechelen, Belgium; 3 October 2022, 22.01 CET, regulated information; Galapagos NV (Euronext & NASDAQ: GLPG) today announced that the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), has adopted a positive opinion on the company's Type II variation application for Jyseleca® (filgotinib), a once-daily, oral, JAK1 preferential inhibitor, to amend the European label regarding testicular function after treatment of patients with inflammatory bowel disease (IBD) and rheumatic conditions (RC).

Dr. Walid Abi-Saab, Chief Medical Officer of Galapagos said, "This positive CHMP opinion marks a key milestone for Jyseleca and provides important information for patients and physicians, given it is the only anti-inflammatory drug that has been evaluated in a robust, large-scale, placebo-controlled trial program for the potential effect on male reproduction. We will now work to update all relevant label information and materials with the aim to increase access to Jyseleca so that European patients who may benefit from the treatment are able to receive it."

The Type II variation application was submitted to the EMA in June 2022, supported by interim data on the primary, secondary and exploratory endpoints at Week 13 and 26 for subjects who met a prespecified sperm decrease at these timepoints (up to Week 52) from the ongoing MANTA and MANTA-RAy studies, investigating the potential effect of filgotinib use on semen parameters and sex hormones in adult patients with IBD and various RC.

Following assessment of the interim data by the CHMP, it was concluded in the opinion that the data did not reveal a difference between treatment groups in the proportion of patients who had a 50% or more decrease from baseline in semen parameters at week 13 (pooled primary endpoint: filgotinib 6.7%, placebo 8.3%) and at week 26. Further, CHMP concluded that the data did not show any relevant changes in sex hormone levels or change from baseline in semen parameters across treatment groups. Overall, CHMP concluded that these clinical data were not suggestive of filgotinib-related effects on testicular function.

Following the positive CHMP opinion, the language in the section of the Special Warnings and Precautions about the potential effect of filgotinib on sperm production and male fertility will be removed from the Summary of Product Characteristics (SmPC), and the MANTA/MANTA-RAy studies will be removed from the Risk Management Plan (RMP).

The design of the MANTA and MANTA-RAy studies was published in *Advances in Therapy* in June 2022[2], and Galapagos is planning to publish the results in a peer-reviewed medical journal next year.

About filgotinib
Filgotinib is marketed as Jyseleca (200mg and 100mg tablets) in the European Union (incl. Norway), Great Britain, and Japan for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have responded inadequately or are intolerant to one or more disease modifying anti-rheumatic drugs (DMARDs). Filgotinib is also marketed as Jyseleca (200mg tablets) in the European Union (incl. Norway), Great Britain, and Japan for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent. A global Phase 3 program with filgotinib is ongoing in Crohn's Disease. More information about clinical trials can be accessed at https://www.clinicaltrials.gov.

The European Summary of Product Characteristics for filgotinib, which includes contraindications and special warnings and precautions, is available at www.ema.europa.eu. The Great Britain Summary of Product Characteristics for filgotinib can be found at www.medicines.org.uk/emc and the Northern Ireland Summary of Product Characteristics for filgotinib can be found at www.emcmedicines.com/en-GB/northernireland, respectively. The interview form from the Japanese Ministry of Health, Labour and Welfare is available at www.info.pmda.go.jp.

Jyseleca® is a trademark of Galapagos NV and Gilead Sciences, Inc. or its related companies. Except for filgotinib's approval as Jyseleca for the treatment of moderately to severely RA and UC by the relevant regulatory authorities in the European Union, Great Britain, and Japan, our drug candidates are investigational; their efficacy and safety have not been fully evaluated by any regulatory authority.

About the MANTA and MANTA-RAy studies
MANTA is a long-term, placebo-controlled Phase 2 safety study in men with moderately to severely active ulcerative colitis (UC) or Crohn's disease (CD) to assess semen parameters while taking filgotinib. MANTA-RAy is a similar study in men with active rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis or non-radiographic axial spondylarthritis. These studies were designed with the input of the relevant health authority and are not powered for statistical comparison between groups. For the primary endpoint analysis, databases of both studies were pooled, and the results were announced in March 2021.

About Galapagos
Galapagos is a fully integrated biotechnology company focused on discovering, developing, and commercializing innovative medicines. We are committed to improving patients' lives worldwide by targeting diseases with high unmet needs. Our R&D

capabilities cover multiple drug modalities, including small molecules and cell therapies. Our portfolio comprises discovery through to Phase 4 programs in inflammation, oncology, fibrosis, and other indications. Our first medicine for rheumatoid arthritis and ulcerative colitis is available in the European Union, Norway, Great Britain, and Japan. For additional information, please visit www.glpg.com or follow us on LinkedIn or Twitter.

Contact
Investors:
Sofie Van Gijsel
Head of Investor Relations
+1 781 296 1143

Sandra Cauwenberghs
Director Investor Relations
+32 495 58 46 63
ir@glpg.com

Media:
Marieke Vermeersch
Head of Corporate Communication
+32 479 490 603
media@glpg.com

Forward-looking statements
This press release includes forward-looking statements, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "may," "ensure," "potential," "will," and "plan," as well as similar expressions. Forward-looking statements contained in this release include, but are not limited to, statements regarding Galapagos' plans and strategy with respect to Jyseleca and the MANTA and MANTA-Ray studies. Any forward-looking statements in this release are based on Galapagos management's current expectations and beliefs and are not guarantees of future performance. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause Galapagos' actual results, performance or achievements to be materially different from any historic or future results, performance or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and other factors include, without limitation, the risk that ongoing and future clinical studies with filgotinib may not be completed in the currently envisaged timelines or at all, the inherent risks associated with clinical trial and product development activities, including the filgotinib clinical program and the FINCH 4 LTE study, the inherent risks and 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, including but not limited to the data from the ongoing MANTA and MANTA-RAy trials, may not support registration or further development of filgotinib due to safety, efficacy or other reasons), the risks related to continued regulatory review of filgotinib following approval by relevant regulatory authorities, including EMA's planned safety review of JAK inhibitors used to treat certain inflammatory disorders, the risks that regulatory authorities may require additional post-approval trials of filgotinib or any other product candidates that are approved in the future, Galapagos' reliance on collaborations with third parties (including our collaboration partner for filgotinib, Gilead) and that Galapagos' estimations regarding its filgotinib development program and regarding the commercial potential of filgotinib may be incorrect, the risk that Galapagos will not be able to continue to execute on its currently contemplated business plan and/or will need to revise its business plan, and risks related to the ongoing COVID-19 pandemic, as well as those risks and uncertainties identified in our most recent Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (SEC), as supplemented and/or modified by any other filings and reports that we have made or will make with the SEC in the future. Given these risks and uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. In addition, even if Galapagos' results, performance or achievements are consistent with such forward-looking statements, they may not be predictive of results, performance or achievements in future periods. These forward-looking statements speak only as of the date of publication of this release. Galapagos expressly disclaims any obligation to update any such forward-looking statements in this release unless required by law or regulation.

---

[1] A Type II variation is defined by EMA as a major change to an existing marketing authorization that may have a significant impact on the quality, safety or efficacy of a medicine, but does not involve a change to the active substance, its strength or the route of administration

[2] MANTA and MANTA-RAy: Rationale and Design of Trials Evaluating Effects of Filgotinib on Semen Parameters in Patients with Inflammatory Diseases - PubMed (nih.gov)

Attachment

- 221003_GLPG - MANTA T2V_CHMP_press release_Final (https://ml-eu.globenewswire.com/Resource/Download/153098fa-8d43-4c31-9844-682b0708c457)