# 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 2020

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, but excluding the quote of Daniel O'Day and the quote of Onno van de Stolpe 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, 333-231765 and 333-249416).

On December 15, 2020, 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 15, 2020

# **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 15, 2020

/s/ Xavier Maes
Xavier Maes
Company Secretary

Gilead and Galapagos announce New Commercialization and Development Agreement for Jyseleca® (filgotinib)

- -- Gilead will Not Advance Jyseleca for the Treatment of Rheumatoid Arthritis (RA) in the U.S. Following FDA Type A Meeting --
- -- Galapagos to Assume Sole Responsibility in Europe for Jyseleca in RA and Ulcerative Colitis (UC) Plus Future Indications; Gilead to Receive Royalties on European Sales Starting in 2024 --
- -- Galapagos to Assume Responsibility for Majority of Ongoing Clinical Trials --
- -- Gilead will Pay Galapagos €160 million to Support Ongoing Development and Accelerated Commercial Buildout in EU --

Galapagos webcast presentation tomorrow, 16 December 2020, at 14:00 CET / 8 AM ET, www.glpg.com +32 2 793 38 47, code 7689939

**Foster City, Calif., and Mechelen, Belgium, December 15, 2020, 22.15 CET; regulated information** – Gilead Sciences, Inc. (Nasdaq: GILD) and Galapagos NV (Euronext & Nasdaq: GLPG) today announced that the companies have agreed to amend their existing arrangement for the commercialization and development of Jyseleca (filgotinib). This announcement follows a Type A meeting with the U.S. Food and Drug Administration (FDA) to discuss the points raised in the Complete Response Letter (CRL) related to the New Drug Application (NDA) for filgotinib in the treatment of RA.

Based on the feedback received from the FDA during the NDA review process and in the Type A meeting, Gilead will not pursue FDA approval of filgotinib for RA. While both Gilead and Galapagos continue to believe in the clinical profile of the 200 mg dose, Gilead has concluded that this dose is required to be competitive in RA in the United States and that the 200 mg dose is unlikely to achieve approval for RA in the U.S. without conducting substantial additional clinical studies.

Under the new arrangement between the companies, Galapagos will assume sole responsibility in Europe for filgotinib in RA, where 200 mg and 100 mg doses are approved for the treatment of moderate to severe RA, and in all future indications. Galapagos will receive payments from Gilead in connection with changes in responsibility for the commercialization and development of filgotinib in Europe and Gilead will receive royalties from European sales of filgotinib. This is an acceleration of the commercial strategy in place for products under the separate ten-year research and development collaboration between the companies, where Galapagos is also responsible for European commercialization.

Through a phased transition including the transfer of filgotinib's marketing authorization to Galapagos, the majority of activities supporting filgotinib in Europe are expected to be assumed by Galapagos by the end of 2021. Under the new operating model, Gilead will retain commercial rights and remain marketing authorization holder for filgotinib outside of Europe, including in Japan where filgotinib has recently been approved, and is co-marketed with Eisai.

"While we believe that the clinical profile of Jyseleca could help many patients living with RA, we no longer see a viable path to U.S. approval in this indication," said Daniel O'Day, Chairman and Chief Executive Officer, Gilead Sciences. "In this new context, Gilead and Galapagos believe it makes sense for Galapagos to drive commercialization in Europe. We are confident that through our strategic alliance with Galapagos, we will deliver many important new therapies for inflammatory diseases in the future."

"Jyseleca is already providing an important new treatment option, making a difference to the lives of patients living with RA, where it is available in Europe," said Onno van de Stolpe, Chief Executive Officer of Galapagos. "While we are very disappointed by the outcome of the FDA meeting, we are excited that we can now accelerate the plan for Galapagos to lead on commercial activities in Europe in our ongoing collaboration with Gilead, and fully leverage the commercial organization Galapagos has built for the Jyseleca launch. This is an important new chapter in Galapagos' ongoing journey to be a leading European biotech company in inflammation and fibrosis."

# **Filgotinib Development**

Under the terms of the amended agreement, Galapagos will assume operational responsibility for ongoing clinical trials evaluating filgotinib in RA. Gilead and Galapagos recently paused clinical trials of filgotinib in psoriatic arthritis (PsA), ankylosing spondylitis (AS), and non-infectious uveitis following receipt of the CRL and, without a viable path forward in the United States, the companies no longer believe it is feasible to continue the current global development program for filgotinib in these indications. As a result, these trials will be stopped over the coming months.

Week 26 data from the MANTA and MANTA-RAy studies, including primary and key secondary endpoints, will be available by mid-2021 and the parties expect to submit the data to regulatory authorities shortly thereafter. In order to complete their review of filgotinib in RA or other future indications, the FDA has requested up to Week 52 follow-up data for patients who show >50% decrease in semen parameters by Week 26 and do not recover in the ongoing MANTA and MANTA-RAy studies.

Gilead and Galapagos will continue to investigate the potential for filgotinib to support patients living with Inflammatory Bowel Disease (IBD). Gilead will retain operational responsibility for the current trials in Crohn's disease while Galapagos will assume operational responsibility for ongoing trials in UC. Filgotinib is currently under review by the European Medicines Agency (EMA) for the treatment of UC and is expected to be submitted to the Japanese Ministry of Health, Labour and Welfare in the

first half of 2021. Gilead and Galapagos expect to have further clarity on the potential U.S. filing of filgotinib in IBD, after consultation with FDA, including on the results of the MANTA and MANTA-RAy studies as described above.

#### **Financial Terms of the Agreement**

Under the terms of the new arrangement, Galapagos will assume all development, manufacturing, commercialization and certain other rights for filgotinib in Europe. The transfer will be subject to applicable local legal, regulatory and consultation requirements. The parties intend to transfer most activities by December 31, 2021 and complete the transition by December 31, 2022. Beginning on January 1, 2021, Galapagos will bear the future development costs for certain studies, in lieu of the equal cost split contemplated by the previous agreement. These studies include the DARWIN3, FINCH4, FILOSOPHY, and Phase 4 studies and registries in RA, MANTA and MANTA-RAy, the PENGUIN1 and 2 and EQUATOR2 studies in PsA, the SEALION1 and 2 studies in AS, the HUMBOLDT study in uveitis in addition to other clinical and non-clinical expenses supporting these studies and support for any investigator sponsored trials in non-IBD conditions and non-clinical costs on all current trials. The existing 50/50 global development cost sharing arrangement will continue for the following studies: SELECTION and its long-term extension study (LTE) in UC, DIVERSITY and its LTE, DIVERGENCE 1 and 2 and their LTEs and support for Phase 4 studies and registries in Crohn's disease, pediatric studies and their LTEs in RA, UC and Crohn's disease, and support for investigator sponsored trials in IBD.

All commercial economics on filgotinib in Europe will transfer to Galapagos as of January 1, 2022, subject to payment of tiered royalties of 8 to 15 percent of net sales in Europe to Gilead, starting in 2024. In connection with the amendments to the existing arrangement for the commercialization and development of filgotinib, Gilead has agreed to irrevocably pay Galapagos €160 million, which will be split between a €110 million payment in 2021 and a €50 million payment in 2022 and is subject to certain adjustments for higher than budgeted development costs. In addition, Galapagos will no longer be eligible to receive any future milestone payments relating to filgotinib in Europe. Gilead expects to recognize the full amount of these payments in its R&D expenses in the fourth quarter of 2020.

# **Information on Related Party Transaction**

The following information is provided by Galapagos pursuant to article 7:116, paragraph 4 of the Belgian Companies and Association Code in connection with the term sheet that has been entered into between Gilead Sciences, Inc. and Galapagos NV on 15 December 2020. For a summary of the main terms of the term sheet and the amended terms of the parties' existing agreement for the commercialization and future development of filgotinib, see above in this press release. These terms and amendments will be reflected in new agreements that will be entered into by Gilead and Galapagos on the basis of the term sheet.

Gilead has two representatives on the supervisory board of Galapagos (Daniel O'Day and Linda Higgins). In addition, Gilead holds (indirectly, through one of its subsidiaries) more than 25% of the shares in Galapagos. Hence, Gilead is considered a "related party" of Galapagos in accordance with the International Financial Reporting Standards as adopted by the European Union. In view hereof, the supervisory board of Galapagos applied the procedure of article 7:116 of the Belgian Companies and Association Code in connection with the approval of term sheet with Gilead. The two representatives of Gilead on the supervisory board of Galapagos did not participate in the deliberation and voting by the supervisory board in relation to the term sheet.

Within the context of the aforementioned procedure, a committee of three independent members of the supervisory board of Galapagos (the Committee) issued an advice to the supervisory board in which the Committee assessed the term sheet. In its advice to the supervisory board, the Committee concluded the following: "The Committee believes that under the circumstances the proposed amendments to Filgotinib Agreements are in the interest of Galapagos and all of its shareholders, and fully aligned with the long-term strategy of Galapagos. The proposed amendments offer an important opportunity to accelerate the plan for Galapagos to lead on commercial activities in Europe for future compounds in its ongoing R&D collaboration with Gilead, and to bolster and further leverage the commercial organization Galapagos has built for the launch of filgotinib. The return of the rights and responsibilities for filgotinib to Galapagos also comes with a number of challenges and risks in terms execution and operation, but these are not unreasonable and can be managed going forward. The Committee therefore believes that the proposed amendments to the collaboration with Gilead, are in the interest of Galapagos, and in any event not manifestly abusive. In view hereof, the Committee issues a favorable and unqualified opinion to the supervisory board of Galapagos." The supervisory board did not deviate from the Committee's advice.

The assessment by the statutory auditor of Galapagos of the advice of the committee and the minutes of the supervisory board is as follows: "Based on our review, we have noted no material inconsistency between the accounting and financial information included in the minutes of the supervisory board and in the advice of the ad hoc committee of the independent members of the supervisory board compared to the information that we, as the Company's statutory auditor, have within the framework of our mandate."

## **About Jyseleca (filgotinib)**

Filgotinib is approved and marketed as Jyseleca (200 mg and 100 mg tablets) in Europe and Japan for the treatment of adults with moderately to severely active RA who have responded inadequately or are intolerant to one or more disease modifying anti-rheumatic drugs (DMARDs). Filgotinib may be used as monotherapy or in combination with methotrexate (MTX). The European Summary of Product Characteristics for filgotinib, which includes contraindications and special warnings and precautions, is available at www.ema.europa.eu. The interview form from the Japanese Ministry of Health, Labour and Welfare is available at www.info.pmda.go.jp. Filgotinib was submitted to the European Commission for an extended indication for the treatment of

adults with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent.

#### **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.

## **About Galapagos**

Galapagos NV discovers, develops and commercializes 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. Our pipeline comprises discovery through Phase 3 programs in inflammation, fibrosis and other indications. Our ambition is to become a leading global biotech company focused on the discovery, development and commercialization of innovative medicines. More information at www.glpg.com.

This press release contains inside information within the meaning of Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (market abuse regulation).

#### **Conference call and Webcast presentation**

Galapagos will conduct a conference call open to the public tomorrow, 16 December 2020, at 14:00 CET / 8 AM ET, which will also be webcasted. To participate in the conference call, please call one of the following numbers ten minutes prior to commencement:

CODE: 7689939

Standard International:+44 (0) 2071 928338USA:+1 646 741 3167UK:+44 844 481 9752Netherlands:+31 207 95 66 14France:+33 1 70 70 0781Belgium:+32 2 793 38 47

A question and answer session will follow the presentation. Go to www.glpg.com to access the live audio webcast. The archived webcast will also be available for replay shortly after the close of the call.

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

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, related to Gilead, Galapagos, the filgotinib collaboration and the ten-year research and development collaboration that are subject to risks, uncertainties and other factors, including the ability of the companies to complete the transaction in a timely manner or at all, including the ability to successfully transition the commercialization of filgotinib in Europe from Gilead to Galapagos in the anticipated timelines; difficulties or unanticipated expenses in connection with implementing the transaction; the risk that Gilead may not realize any anticipated benefits from the collaborations; the potential effects on Gilead's revenues and earnings; the ability of the companies to discover, develop and commercialize any products under the collaborations, including the ability of the companies to commercialize filgotinib or develop and commercialize filgotinib for additional indications; the ability of the companies to initiate and complete clinical trials involving any product candidates under the collaborations, including filgotinib, in the currently anticipated timelines or at all; the possibility of unfavorable results from ongoing and additional clinical trials involving any product candidates under the collaborations, including filgotinib; uncertainties relating to regulatory applications and related filing and approval timelines, including the risk that EMA may not approve filgotinib for the treatment of UC in the anticipated timelines or at all, and any marketing approvals, if granted, may have significant limitations on its use; the possibility that the companies may make a strategic decision to discontinue development of involving any product candidates under the collaborations, including filgotinib for the treatment of RA, UC, PsA, AS, noninfectious uveitis, IBD, Crohn's disease or other indications, and as a result, such products may never be successfully commercialized; and the accuracy of any assumptions underlying any of the foregoing. These and other risks are described in detail in Gilead's periodic reports filed with the U.S. Securities and Exchange Commission, including current reports on Form 8-K, quarterly reports on Form 10-Q and annual reports on Form 10-K. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including all statements regarding the intent, belief or current expectation of the companies and members of their senior management team. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties and are cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

#### **Galapagos Forward-Looking Statement**

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, that are subject to risks, uncertainties and other factors that could cause actual results to differ materially from those referred to in the forward-looking statements and, therefore, the reader should not place undue reliance on them. These risks, uncertainties and other factors include, without limitation, the risk that the parties would not be able to complete the contemplated transaction in a timely manner or at all, the risk that parties may not be able to successfully implement the transaction and transfer of rights and activities in a timely or efficient manner or at all, taking into account the need to fulfil applicable local legal, regulatory and consultation requirements and other integration risks and expenses, that Galapagos' expectations regarding the costs and revenues associated with the transfer of European commercialization rights to filgotinib may be incorrect, inherent risks associated with clinical trial and product development activities, competitive developments, and regulatory approval requirements, including the risk that data from the ongoing and planned clinical research programs with filgotinib may not support registration or further development for UC, IBD, RA, or other indications due to safety, efficacy or other reasons, the timing or likelihood of regulatory authorities' approval of marketing authorization for filgotinib for UC, IBD, RA, or other indications, including the risk of such regulatory authorities requiring additional studies, Galapagos' reliance on collaborations with third parties, including the collaboration with Gilead, the uncertainty regarding estimates of the commercial potential of filgotinib, the risks and costs involved in selling and marketing filgotinib, the possibility that the companies may make a strategic decision to discontinue development of any product candidates under the collaborations, including filgotinib for the treatment of RA, UC, PsA, AS, non-infectious uveitis, IBD, Crohn's disease or other indications, and as a result, such products may never be successfully commercialized, as well as those risks and uncertainties identified in our Annual Report on Form 20-F for the year ended 31 December 2019 and our subsequent filings with the SEC. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The forward-looking statements contained herein are based on management's current expectations and beliefs and speak only as of the date hereof, and Galapagos makes no commitment to update or publicly release any revisions to forward-looking statements in order to reflect new information or subsequent events, circumstances or changes in expectations.

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