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**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**

**September 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, except for the quote of Dr. Peter C. Taylor, the quote of Mr. Daniel O'Day, and the quote of Mr. 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 and 333-231765).

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On September 25, 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 September 25, 2020](#)

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## 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 25, 2020

/s/ Xavier Maes  
Xavier Maes  
Company Secretary

**EUROPEAN COMMISSION GRANTS MARKETING AUTHORIZATION FOR JYSELECA® (FILGOTINIB)  
FOR THE TREATMENT OF ADULTS WITH MODERATE TO SEVERE ACTIVE RHEUMATOID  
ARTHRITIS**

*-- Jyseleca® Demonstrated Durable Efficacy Combined with a Consistent Safety Profile in Rheumatoid Arthritis Through 52 Weeks in Phase 3 Clinical Development Program --*

**Foster City, Calif., & Mechelen, Belgium, September 25, 2020, 19.00 CET** – Gilead Sciences, Inc. (Nasdaq: GILD) and Galapagos NV (Euronext & Nasdaq: GLPG) today announced that the European Commission (EC) has granted marketing authorization for Jyseleca® (filgotinib 200 mg and 100 mg tablets), a once-daily, oral, JAK1 inhibitor for the treatment of adults with moderate to severe active rheumatoid arthritis (RA) who have responded inadequately to, or are intolerant to, one or more disease modifying anti-rheumatic drugs (DMARDs). Jyseleca may be used as monotherapy or in combination with methotrexate (MTX).<sup>1</sup>

RA is a chronic, progressive, systemic, inflammatory disease that can lead to significant and irreversible joint destruction, pain and functional impairment.<sup>2</sup> Almost 3 million people in Europe are living with RA,<sup>3</sup> many of whom do not achieve long-term symptom control, which can lead to more frequent symptom flares and disease progression and can significantly impact their quality of life.<sup>4,5</sup>

“Despite the availability of existing therapies, new treatment options are still needed to help optimally manage the impact of RA on patients’ daily lives. Jyseleca has demonstrated robust symptom control and prevention of disease progression with a consistent safety profile across the clinical development program. This marketing authorization provides a welcome new option for people in Europe living with this debilitating and complex disease,” said Peter C. Taylor, MA, BM, BCh, PhD, FRCP, Professor of Musculoskeletal Sciences at the University of Oxford.

The EC’s decision is supported by data from more than 3,500 patients treated with Jyseleca across the Phase 3 FINCH and Phase 2 DARWIN programs.<sup>6</sup> In the FINCH studies, Jyseleca consistently achieved ACR20/50/70 criteria, with improvements in all individual ACR components compared with placebo or MTX.<sup>7-8,9,10,11,12,13</sup>

A significantly higher proportion of patients treated with Jyseleca 200 mg plus MTX or other conventional synthetic disease-modifying anti-rheumatic drug(s) (csDMARD) achieved low disease activity and/or remission (DAS28-CRP $\leq$ 3.2 and DAS28-CRP $<$ 2.6) at Weeks 12 and 24 compared with placebo or MTX.<sup>7-13</sup>

In patients who had an inadequate response to MTX, treatment with Jyseleca plus MTX achieved statistically significant inhibition of progression of structural joint damage compared with placebo plus MTX, as assessed using the modified Total Sharp Score (mTSS) at Week 24. In the DARWIN 3 Phase 2, open-label, long-term extension study, durable ACR20/50/70 responses were maintained for up to three years in patients who received Jyseleca 200 mg as monotherapy or with MTX.<sup>1</sup>

Across the FINCH and DARWIN trials,<sup>14</sup> the most common adverse reactions were nausea, upper respiratory tract infection, urinary tract infection and dizziness.<sup>1</sup> Rates of herpes zoster and pneumonia were uncommon.<sup>1</sup> The frequency of serious infections in the Jyseleca 200 mg group was 1.0 percent compared with 0.6 percent in the placebo group.<sup>1</sup>

In an integrated safety analysis in seven clinical trials the rates of major adverse cardiac events (MACE) and venous thromboembolism (VTE) with Jyseleca were comparable to placebo.<sup>6</sup> The rates of serious infections remained stable with long-term exposure.<sup>1</sup>

“Jyseleca, the first medicine from Galapagos to obtain regulatory approval is the result of a strong commitment to addressing unmet medical need,” said Daniel O’Day, Chairman and Chief Executive Officer, Gilead Sciences. “We look forward to making continued progress through our collaboration with Galapagos so we can help to deliver many new solutions for patients in the future.”

“Today’s announcement is a proud day for everyone at Galapagos, recognizing years of research and commitment to make a meaningful change in the lives of patients struggling with the symptoms of RA,” said Onno van de Stolpe, Chief Executive Officer, Galapagos. “This news further affirms the efficacy and safety profile of Jyseleca, and we look forward to bringing this important treatment to physicians and patients across Europe as quickly as possible.”

Under the collaboration agreement, Galapagos will now receive a milestone payment of \$75 million in recognition of the approval of Jyseleca by the European Commission.

**About the FINCH Program**

The FINCH Phase 3 program investigated the efficacy and safety of Jyseleca 200 mg and 100 mg once-daily, in RA patient populations ranging from early stage to biologic-experienced patients. FINCH 1 was a 52-week, randomized, placebo- and adalimumab-controlled trial in combination with MTX, enrolling 1,759 adult patients with moderate to severe active RA who had inadequate response to MTX. The primary endpoint in FINCH 1 was ACR20 at Week 12. The trial included radiographic

assessment at Weeks 12, 24 and 52. FINCH 2 was a global, 24-week, randomized, double-blind, placebo-controlled, Phase 3 study evaluating Jyseleca on a background of csDMARDs among 449 adult patients with moderate to severe active RA who had not adequately responded to biologic DMARDs (bDMARDs). The primary endpoint in FINCH 2 was ACR20 at Week 12. FINCH 3 was a 52-week, randomized trial in 1,252 MTX-naïve patients to evaluate Jyseleca 200 mg alone and Jyseleca 200 mg or 100 mg combined with MTX versus MTX alone in MTX-naïve patients. The primary endpoint in FINCH 3 was ACR20 at Week 24. The trial included radiographic assessment at Weeks 24 and 52.

### **About the Filgotinib Collaboration**<sup>15</sup>

Gilead and Galapagos NV are collaborative partners in the global development and commercialization of filgotinib in RA and other inflammatory indications. The companies are conducting global studies investigating the potential role of Jyseleca in a variety of diseases, including the previously reported Phase 3 SELECTION trial in ulcerative colitis.

More information about clinical trials with Jyseleca can be accessed at: [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **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](http://www.gilead.com).

### **About Galapagos**

Galapagos NV discovers and develops small molecule medicines with novel modes of action, three 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, osteoarthritis and other indications. Our 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](http://www.glp.com).

### **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. There is also the possibility of unfavorable results from ongoing and additional clinical trials involving filgotinib. Further, it is possible that the parties may make a strategic decision to discontinue development of filgotinib, and as a result, filgotinib may never be successfully commercialized. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. 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 Form 10-Q for the quarter ended June 30, 2020, 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.

### **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 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 due to safety, efficacy or other reasons, the timing or likelihood of additional regulatory authorities approval of marketing authorization for filgotinib, such additional regulatory authorities requiring additional studies, Galapagos' reliance on collaborations with third parties, including the collaboration with Gilead for filgotinib, the uncertainty regarding estimates of the commercial potential of filgotinib, 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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*Full European Summary of Product Characteristics for Jyseleca are available from the EMA website at [www.ema.europa.eu](http://www.ema.europa.eu).*

*Jyseleca<sup>®</sup>, Gilead and the Gilead logo are trademarks of Gilead Sciences, Inc. or its related companies.*

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<sup>1</sup>Summary of Product Characteristics for Jyseleca<sup>®</sup>, Foster City, USA: Gilead Sciences.

<sup>2</sup>Centers for Disease Control and Prevention. Rheumatoid Arthritis (RA). Available at: <https://www.cdc.gov/arthritis/basics/rheumatoid-arthritis.html>. Accessed: September 2020.

<sup>3</sup>National Rheumatoid Arthritis Society (NRAS). European Fit for Work report. Available at: <https://www.nras.org.uk/european-fit-for-work-report>. Accessed: September 2020.

<sup>4</sup>Claxton, L. et al. An economic evaluation of tofacitinib treatment in rheumatoid arthritis after methotrexate or after 1 or 2 TNF inhibitors from a US payer perspective. *Journal of Managed Care & Specialty Pharmacy*. 2018;13:1-8. doi: 10.18553/jmcp.2018.17220.

<sup>5</sup>Smolen, J.S. et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Annals of Rheumatic Disease*. 2017;79:685-699. doi: 10.1136/annrheumdis-2019-216655.

<sup>6</sup>Genovese, M C et al. Integrated safety Analysis of Filgotinib Treatment for Rheumatoid Arthritis from 7 Clinical Trials. Abstract European Congress of Rheumatology (EULAR) 2020.

<sup>7</sup>Kivitz, A. et al. Filgotinib provided rapid and sustained improvements in functional status, pain, health-related quality of life, and fatigue in patients with rheumatoid arthritis and inadequate response to methotrexate: results from the FINCH 1 study. Abstract European Congress of Rheumatology (EULAR) 2020.

<sup>8</sup>Combe, B. et al. Efficacy and safety of Filgotinib for patients with rheumatoid arthritis with inadequate response to methotrexate: FINCH 1 52-week results. Abstract ACR/ARP Annual Meeting 2019.

<sup>9</sup>Combe, B. et al. LB0001 efficacy and safety of Filgotinib for patients with rheumatoid arthritis with inadequate response to methotrexate: FINCH 1 primary outcome results. *Annals of the Rheumatic Diseases*. 2019;78:77-78.

<sup>10</sup>Genovese, M. et al. Effect of Filgotinib vs placebo on clinical response in patients with moderate to severe rheumatoid arthritis refractory to disease-modifying antirheumatic drug therapy: the FINCH 2 randomized clinical trial [published correction appears in *JAMA*. 2020 Feb 4;323(5):480]. *JAMA*. 2019;322(4):315-325. doi:10.1001/jama.2019.9055.

<sup>11</sup>Westhovens, R. et al. Efficacy and safety of Filgotinib in methotrexate-naïve patients with rheumatoid arthritis: FINCH 3 52-week results, *Annals of the Rheumatic Diseases* 2020;79:1019-1020.

<sup>12</sup>Alten, R. et al. Filgotinib provided rapid and sustained improvements in functional status, pain, and health related quality of life, and reduced fatigue over time in patients with rheumatoid arthritis who are methotrexate-naïve: results from the FINCH 3 study. Abstract European Congress of Rheumatology (EULAR) 2020.

<sup>13</sup>Westhovens, R. et al. LB0003 efficacy and safety of Filgotinib for patients with rheumatoid arthritis naïve to methotrexate therapy: FINCH 3 primary outcome results. *Annals of the Rheumatic Diseases*. 2019;78:259-261.

<sup>14</sup>Frequency based on placebo controlled pre rescue period (week 12) pooled across FINCH 1 and 2, and DARWIN 1 and 2, for patients who received Filgotinib 200 mg. Summary of Product Characteristics for Jyseleca<sup>®</sup> (table 2). Foster City, USA: Gilead Sciences.

<sup>15</sup> Gilead & Galapagos Filgotinib Clinical Program Trial Details: FINCH 1 ([NCT02889796](#)); FINCH 2 ([NCT02873936](#)); FINCH 3 ([NCT02886728](#)); SELECTION ([NCT02914522](#)); DIVERSITY ([NCT02914561](#)); PENGUIN 1 ([NCT04115748](#)); PENGUIN 2 ([NCT04115839](#)).