**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 February 2023**

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 quotes of Prof. Dr. Séverine Vermeire and Daniele D'Ambrosio, MD, PhD, contained in 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, 333-260500, and 333-268756).

On February 8, 2023, 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 February 8, 2023

## 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: February 8, 2023

/s/ Annelies Denecker
Annelies Denecker
Company Secretary

**EXHIBIT 99.1**

**Galapagos announces topline results from Phase 3 DIVERSITY trial of filgotinib in Crohn's disease**

- The two induction cohorts missed the co-primary endpoints of clinical remission and endoscopic response at Week 10
- In the maintenance phase, filgotinib 200mg once daily achieved the co-primary endpoints of clinical remission and endoscopic response at Week 58
- The safety findings were generally consistent with the known profile of filgotinib in rheumatoid arthritis (RA) and ulcerative colitis (UC)
- Galapagos decided not to submit a Marketing Authorization Application in Europe based on these topline data
- Galapagos remains fully committed to filgotinib, a JAK1 preferential inhibitor orally administered once daily, and its approved indications, RA and UC, and is on track to start a Phase 3 trial in axial spondyloarthritis (AxSpA) later this year

**Mechelen, Belgium; 8 February 2023, 22:01 CET; regulated information; Galapagos NV (Euronext & NASDAQ: GLPG) today announced the topline results from DIVERSITY, a global Phase 3 trial to evaluate the safety and efficacy of filgotinib, 100mg or 200mg once daily, during induction and maintenance treatment of biologic-naïve and biologic-experienced patients with moderate to severe Crohn's disease (CD).**

The co-primary endpoints at Week 10 and Week 58 were clinical remission per Patient Reported Outcome (PRO-2) and endoscopic response per Simple Endoscopic Score for Crohn's Disease (SES-CD).

Induction Cohort A included biologic-naïve (54%) and biologic-experienced (46%) patients; induction Cohort B included biologic-experienced patients. In total, 33% of patients in Cohort A and 52% of patients in Cohort B had failed treatment with 3 or more biologic drugs.

Both induction cohorts of the study failed to meet the co-primary endpoints of clinical remission and endoscopic response for filgotinib, 100mg and 200mg once daily.

In the maintenance phase of the study, a statistically significant higher proportion of patients receiving filgotinib 200mg once daily achieved the co-primary endpoints of clinical remission (43.8% vs. 26.4%; p=0.0382) and endoscopic response (30.4% vs. 9.4%; p=0.0038) compared to placebo at Week 58.

The safety observations of the study were in line with the underlying disease and were consistent with the safety profile of filgotinib in previous studies across indications.

"While Crohn's disease is a difficult-to-treat condition and a large proportion of patients enrolled in DIVERSITY had high disease activity and long-standing disease with prior exposure to multiple therapies, we are disappointed with the outcome of the induction studies. However, at the same time, we are encouraged by the confirmed safety profile and the clinical efficacy signs observed in the maintenance phase," said Prof. Dr. Séverine Vermeire, Research Director of the Group Biomedical Sciences, University of Leuven and staff member at the Gastroenterology Department of the University Hospital Leuven, Belgium.

Daniele D'Ambrosio, MD, PhD, Therapeutic Area Head, Immunology, at Galapagos added: "As filgotinib demonstrated robust late-stage clinical data in UC[1] and in earlier Phase 2 clinical studies in CD, we are very disappointed with this outcome. The current topline data do not support a Marketing Authorization Application in Europe, and we will analyze the full results to gain valuable insights to guide future research efforts. Galapagos remains fully committed to filgotinib and its approved indications of RA and UC, and we are on track to initiate a Phase 3 study in patients with AxSpA later this year. We are grateful to the patients and all medical professionals who participated in this trial."

**About Crohn's disease**

Crohn's disease is an inflammatory bowel disease in which the balance of the intestinal immune system is disturbed causing a significant burden on people living with this disease. Crohn's disease is considered to be a progressive disease and causes ulcerations that may affect any part of the digestive system from mouth to anus. The cause of the disease is unknown, with onset usually between the ages of 15 and 35. Patients suffer from abdominal pain, diarrhea (often bloody), vomiting, fever, and weight loss. Estimates suggest there could be up to 1.6 million people living with Crohn's disease across Europe, with up to 78,000 new cases every year.[2] Despite the availability of advanced therapies, insufficient control of inflammation and loss of response over time are still a big problem for many CD patients.[3]

**About the filgotinib clinical development program in Crohn's disease**

DIVERSITY consisted of a combined (induction and maintenance), double-blind, placebo-controlled Phase 3 trial, enrolling 1,374 biologic-naive and biologic-experienced patients with moderately to severely active CD in 384 centers worldwide. The primary objectives of the trial were to evaluate the safety and efficacy of filgotinib 100mg or 200mg, once-daily oral treatment, versus placebo.

The co-primary endpoints at Week 10 and Week 58 were clinical remission per Patient Reported Outcome (PRO-2) and endoscopic response per Simple Endoscopic Score for Crohn's Disease (SES-CD). Clinical remission measured by the Crohn's Disease Activity Index (CDAI) was a key secondary endpoint in the induction and maintenance phase of the study. Additional

secondary endpoints were clinical remission and endoscopic response (combined into a single endpoint on a patient level) at Week 10, clinical remission and endoscopic response (combined into a single endpoint on a patient level) at Weeks 10 and 58, sustained clinical remission and endoscopic response at Weeks 10 and 58, and 6-month corticosteroid-free clinical remission at Week 58.

The results from the previous studies, Phase 2 FITZROY and Phase 2b DIVERGENCE, contributed to the long-term evaluation of filgotinib in Crohn's disease. Full results of the FITZROY study were reported in *The Lancet*.[4] A long-term extension study including patients who participated in DIVERSITY is currently ongoing.

For DIVERSITY trial information, visit: ClinicalTrials.gov Identifier NCT02914561

**About filgotinib**

Filgotinib is marketed as Jyseleca in Europe and Japan for the treatment of adults with moderate to severe 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 in Europe and Japan for the treatment of adult patients with moderate to severe 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. Jyseleca (filgotinib) 100mg and 200mg are registered in the above-mentioned territories.

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.



*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).*

**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 immunology, oncology, and other indications. Our first medicine for rheumatoid arthritis and ulcerative colitis is available in Europe and Japan. For additional information, please visit www.glpg.com or follow us on LinkedIn or Twitter.

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**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 "will," "continue," "ongoing," "estimated," "on track," "remains," "guide," and "recommended," as well as similar expressions. Forward-looking statements contained in this release include, but are not limited to, statements related to our plans and strategy with respect to Jyseleca and filgotinib, statements related to the analysis of data from the DIVERSITY study, statements related to the timing for the start of our planned Phase 3 clinical development in AxSpA, and statements related to interactions with regulatory authorities, and the timing or likelihood of approval for filgotinib in AxSpA. Any forward-looking statements in this release are based on our 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 our 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, the planned Phase 3 clinical development in AxSpA, and the DIVERSITY 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 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 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, our reliance on collaborations with third parties (including our collaboration partner for filgotinib, Gilead) and that our estimations regarding its filgotinib development program and regarding the commercial potential of filgotinib may be incorrect, the risk that we 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 our 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. We expressly disclaim any obligation to update any such forward-looking statements in this release unless required by law or regulation.*

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[1] *The Lancet* Vol 397 No. 10292 p2372-2384. Published: June 3, 2021.

[2] *Journal of Crohn's and Colitis*, Volume 7, Issue 4, May 1, 2013, Pages 322 337, https://doi.org/10.1016/j.crohns.2013.01.010.

[3] https://pubmed.ncbi.nlm.nih.gov/25933126/

[4] *The Lancet* Vol. 389 No. 10066 p266–275 Published: December 14, 2016.