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 quote of Dr. Paul Stoffels, 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 9, 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 9, 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 10, 2023

/s/ Annelies Denecker
Annelies Denecker
Company Secretary

Galapagos presented encouraging initial safety and efficacy data at 2023 EBMT-EHA for point-of-care manufactured CAR-T candidate, GLPG5201, in rrCLL

- All 7 out of 7 eligible patients with relapsed/refractory Chronic Lymphocytic Leukemia, with or without Richter's transformation, responded to treatment (Objective Response Rate of 100%)
- GLPG5201 showed an acceptable safety profile with no cytokine release syndrome (CRS) higher than grade 2, or immune effector cell-associated neurotoxicity syndrome (ICANS) observed

Mechelen, Belgium; 9 February 2023, 22.01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) today presented encouraging data at the European Society for Blood and Marrow Transplantation (EBMT)-European Hematology Association (EHA) 5th European CAR T-cell Meeting in Rotterdam.

CD19-directed CAR-T therapy has the potential to improve survival for patients with a broad range of B-cell malignancies such as Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL).

EUPLAGIA-1 is an ongoing Phase 1/2 study in heavily pre-treated patients with rrCLL and rrSLL, with or without Richter's transformation (RT), to evaluate the safety, efficacy, and feasibility of GLPG5201, a fresh CD19 CAR-T product candidate manufactured at point-of-care. As of 9 January 2023, 7 patients diagnosed with rrCLL (4 patients with RT) were enrolled in the study (n=4 at dose level 1 (DL1); n=3 at dose level 2 (DL2)). All patients received GLPG5201 as a fresh infusion with a median vein-to-vein time of 7 days. The dose levels that are evaluated in the Phase 1 part of the study are $35x10^6$ (DL1), $100x10^6$ (DL2) and $300x10^6$ (dose level 3 (DL3)) CAR+ viable T cells.

The initial results from these 7 patients that were eligible for efficacy analysis (cut-off date: 9 January 2023) indicated that a 7-day vein-to-vein time is feasible and demonstrated strong and consistent *in vivo* CAR-T expansion levels. Moreover, the initial efficacy results are encouraging with an objective response rate (ORR) of 100% observed. 6 out of 7 patients (86%) reached a complete response (CR) and all Richter's patients achieved a CR. A duration of response of up to 7.9 months has been reported and follow-up is ongoing. Only 1 patient (DL1) progressed (progressive disease, PD, after partial response, PR) and had a CD19-negative relapse with confirmed Richter's transformation.

In the safety analysis of these 7 patients, adverse events were consistent with the known toxicities of CD19 CAR-T treatment. None of the patients experienced a cytokine release syndrome (CRS) higher than grade 2 at both dose levels and no immune effector cell associated neurotoxicity syndrome (ICANS) was reported. No dose limiting toxicities (DLTs) were reported and the majority of grade ≥3 adverse events were hematological. Only one serious adverse event was reported at DL2 with a patient experiencing a CRS grade 2, but the event was resolved after 7 days.

"We were very pleased to present strong initial data from the ongoing Phase 1/2 study of our fresh CD19 CAR-T candidate manufactured at point-of-care. This marks an important milestone in our journey to transform the lives of patients with severe blood cancers, including patients with RT, through the acceleration of innovation and breakthrough science", said Dr. Paul Stoffels[1], CEO of Galapagos. "We look forward to reporting Phase 1 topline data around mid-year."

Details of the poster presentation:

Abstract Title	Authors	Presentation date/time
Initial Clinical Results of Euplagia-1, a Phase I/II Trial of Point-of-Care Manufactured GLPG5201 in R/R CLL/SLL with or without Richter's transformation	Nuria Martinez-Cibrian, Sergi Betriu, Valentin Ortiz-Maldonado, Daniel Estban, Leticia Alserawan, Mercedes Montoro, Anna DD van Muyden, Maike Spoon, Margot J. Pont, Christian Jacques, Julio Delgado	Poster Number: CART2023: 206 Date: 9 February 2023, 13:15 CET Session: 704

About point-of-care manufacturing (Cocoon®)

CellPoint has developed, in a strategic collaboration with Lonza, a novel point-of-care supply model, which is designed to enable clinicians to administer fresh CAR-T cells within 7 days of leukapheresis, without complex logistics or cryopreservation, thereby aiming to address important limitations of current CAR-T treatments. The proprietary platform consists of CellPoint's end-to-end xCellit workflow management and monitoring software and Lonza's Cocoon® Platform, a functionally closed, automated manufacturing platform for cell therapies.

About the EUPLAGIA-1 study (EudraCT 2021-003815-25)
EUPLAGIA-1 is an ongoing Phase 1/2 open-label, multi-center study evaluating the feasibility, safety, and efficacy of point-of-care manufactured GLPG5201 in patients with relapsed/refractory Chronic Lymphocytic Leukemia (rrCLL) and Small Lymphocytic Lymphoma (rrSLL), with or without Richter's transformation (RT). GLPG5201 is a second generation anti-CD19/4-1BB CAR-T product candidate, administered as intravenous infusion of a fresh product candidate in a single fixed dose. Patients with CD19+ rrCLL or rrSLL with >2 lines of therapy are eligible to participate, and patients with RT are eligible regardless of prior therapy. The primary objective of the Phase 1 part of the study is to evaluate safety and determine the

recommended dose for the Phase 2 part of the study. The primary objective of the Phase 2 part of the study is to assess the objective response rate (ORR) and the secondary objectives include the analysis of the complete response rate (CRR), duration of response, progression free survival, overall survival, safety pharmacokinetic profile, and feasibility of point-of-care manufacturing.

The planned dose levels that are evaluated in the Phase 1 part of the study are $35x10^6$ (DL1), $100x10^6$ (DL2) and $300x10^6$ (DL3) CAR+ viable T cells. The study uses a Bayesian Optimal Interval (BOIN) design (n=15 patients) for Phase 1. Following screening and enrolment, patients will receive ibrutinib continuously until leukapheresis of mononuclear cells. During GLPG5201 manufacturing, patients receive cyclophosphamide (300 mg/m^2/day)/fludarabine (30 mg/m^2/day) for 3 days. After a resting period of at least 2 days, GLPG5201 is administered via intravenous infusion. All patients remain hospitalized for at least 7 days and the end-of-study visit is at Week 14 post CAR-T infusion. The study is currently enrolling rrCLL/SLL patients in Europe, including patients with Richter's transformation, and we aim to provide topline results for Phase 1 around mid-2023.

About Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma
Chronic Lymphocytic Leukemia (CLL) is one of the chronic lymphoproliferative disorders (lymphoid neoplasms). It is characterized by a progressive accumulation of functionally incompetent lymphocytes, which are usually monoclonal in origin. Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Leukemia (SLL) are essentially the same type of B-cell Non-Hodgkin lymphoma (NHL), with the only difference the location where the primary cancer occurs. CLL affects B-cells in the blood and bone marrow and SLL cancer cells are located in lymph nodes and/or the spleen[2]. Richter's transformation is an uncommon clinicopathological condition observed in patients with Chronic Lymphocytic Leukemia (CLL). It is characterized by the sudden transformation of the CLL into a significantly more aggressive form of large cell lymphoma, and occurs in approximately 2-10% of all CLL patients. CLL/SLL usually follows an indolent course and is an incurable disease. Patients who develop relapsed and refractory disease and become resistant to new agents have a dismal prognosis and a high unmet medical need for new therapeutic options such as CAR-T cells. With estimated incidence of 4.7 new cases per 100,000 individuals, CLL/SLL are the most prevalent lymphoid malignancy and are the most common adult leukemias in the US and in Europe[3].

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. CellPoint was acquired by Galapagos in June 2022. For additional information, please visit glpg.com or follow us on LinkedIn or Twitter.

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Forward Looking Statements
This press release contains 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 "initial," "feasible," "will," encouraging," "potential," "forward," "aim," promising," "believe," "suggest," "on track," and "planned," as well as any similar expressions. Forward-looking statements contained in this release include, but are not limited to, any statements regarding preliminary, interim and topline data from the EUPLAGIA-1 study and other analyses related to CD19 CAR-T, statements regarding our plans and strategy with respect to the EUPLAGIA-1 study and CD19 CAR-T, statements regarding the expected timing, design and readouts of the EUPLAGIA-1 study, including the expected trial recruitment and timing for topline results from the EUPLAGIA-1 study, statements regarding the collaboration with Lonza, statements regarding our regulatory and R&D outlook, and statements regarding our strategy, portfolio goals, business plans, focus. Of note, the EUPLAGIA-1 study is ongoing and these interim results may not reflect any future or final results or be confirmed upon completion of such study. 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 may involve unknown and known 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 statements. These risks, uncertainties and other factors include, without limitation, the risk that ongoing and future clinical studies may not be completed in the currently envisaged timelines or at all, risks associated with clinical trials, recruitment of patients for trials, and product development activities, including the CD19 CAR-T clinical program and the EUPLAGIA-1 study, the inherent risks and uncertainties associated with competitive developments, risks related to regulatory approval requirements (including, but not limited to, the risk that data from the ongoing

EUPLAGIA-1 study may not support registration or further development due to safety, efficacy concerns, or other reasons), risks related to the acquisition of CellPoint, including the risk that we may not achieve the anticipated benefits of the acquisition of CellPoint, the inherent risks and uncertainties associated with target discovery and validation or drug discovery and development activities, the risk that the preliminary and topline data from the EUPLAGIA-1 study may not be reflective of the final data, risks related to our reliance on collaborations with third parties (including CellPoint's collaboration partner Lonza), the risk that we will not be able to continue to execute on our currently contemplated business plan and/or will revise our business plan, including the risk that our plans with respect to CAR-T may not be achieved on the currently anticipated timeline or at all, and risks related to the ongoing COVID-19 pandemic. A further list and description of these or other risks and uncertainties can be found in our filings and reports with the US Securities and Exchange Commission (SEC), including in our most recent annual report on Form 20-F filed with the SEC and our subsequent filings and reports filed with the SEC. 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 forward-looking statements in this release, unless required by law or regulation.

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[1] Acting via Stoffels IMC BV

[2] Wierda WG. Chronic lymphocytic leukemia/ Small lymphocytic lymphoma fact sheet. In: Foundation LR, editor: https://www.lymphoma.org/wp-content/uploads/2018/04/LRF_FACTSHEET_CLL_SLL.pdf.2018.

[3] Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer Statistics, 2021. CA: A Cancer Journal for Clinicians. 2021;71(1):7-33. https://www.ncbi.nlm.nih.gov/books/NBK493173