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 August 2024

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 [ ]

The information contained in this Report on Form 6-K, including Exhibit 99.1, except for the quote of dr. Paul Stoffels, included 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, 333-268756, and 333-275886).

On August 23, 2024, 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 August 23, 2024

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: August 23, 2024

/s/ Annelies Denecker
Annelies Denecker
Company Secretary

EXHIBIT 99.1

Galapagos announces FDA clearance of IND application for Phase 1/2 ATALANTA-1 study of CD19 CAR-T, GLPG5101, in relapsed/refractory non-Hodgkin lymphoma

Mechelen, Belgium; August 23, 2024, 07:00 CET; regulated information – inside information – Galapagos NV (Euronext & NASDAQ: GLPG) today announced that the U.S. Food and Drug Administration (FDA) has cleared Galapagos' Investigational New Drug (IND) application for ATALANTA-1, a Phase 1/2 multicenter study evaluating the feasibility, safety, and efficacy of GLPG5101 in patients with relapsed/refractory non-Hodgkin lymphoma (R/R NHL).

GLPG5101 is an autologous CD19 CAR-T cell therapy product candidate produced using Galapagos' innovative decentralized cell therapy manufacturing platform with the potential for the administration of fresh, fit cells within a median vein-to-vein time of seven days.

The primary objective of the Phase 1 part of ATALANTA-1 is to evaluate the safety and preliminary efficacy of GLPG5101 to determine the recommended dose for Phase 2. Secondary objectives include assessment of efficacy and feasibility of decentralized manufacturing of GLPG5101. The primary objective of the Phase 2 study is to evaluate the objective response rate. The secondary objectives include complete response rate, duration of response, progression free survival, overall survival, safety, pharmacokinetic profile, and the feasibility of decentralized manufacturing. Each enrolled patient will be followed for 24 months.

The Phase 1/2 ATALANTA-1 study is currently ongoing in Europe, and early data have shown encouraging results in patients with R/R NHL.[1]

"We are dedicated to accelerating breakthrough innovation that extends the reach of cell therapies to patients with rapidly progressing cancers," said Dr. Paul Stoffels[2], Galapagos' CEO and Chairman of the Board of Directors. "Our innovative, decentralized manufacturing platform is designed to overcome many of the challenges faced by existing CAR-T production methods. The Galapagos platform has the potential for greater speed and scalability, with the delivery of fresh, fit cells with a median vein-to-vein time of seven days, close to patients. The IND clearance for the Phase 1/2 study of GLPG5101 marks a significant milestone in our cell therapy clinical program, bringing us one step closer to offering our CD19 CAR-T cell therapy to patients in the U.S."

About non-Hodgkin lymphoma and GLPG5101
GLPG5101 is a second generation anti-CD19/4-1BB CAR-T product candidate, administered as a single fixed intravenous dose. It is currently being assessed in the ATALANTA-1 Phase 1/2, open-label, multicenter study to evaluate the safety, efficacy and feasibility of decentralized manufactured GLPG5101 in patients with relapsed/refractory non-Hodgkin lymphoma (R/R NHL). Non-Hodgkin lymphoma is a cancer originating from lymphocytes, a type of white blood cell which is part of the body's immune system. Non-Hodgkin lymphoma can occur at any age although it is more common in adults over 50 years old. Initial symptoms usually are enlarged lymph nodes, fever, and weight loss. There are many different types of non-Hodgkin lymphoma. These types can be divided into aggressive (fast-growing) and indolent (slow growing) types, and they can be formed from either B lymphocytes (B cells) or in lesser extent from T lymphocytes (T cells) or Natural Killer cells (NK cells). B-cell lymphoma makes up about 85% of non-Hodgkin lymphomas diagnosed in the US. Prognosis and treatment of non-Hodgkin lymphoma depend on the stage and type of disease.

About Galapagos' cell therapy manufacturing platform
Galapagos' innovative, decentralized cell therapy manufacturing platform has the potential for the administration of fresh, fit cells within a median vein-to-vein time of seven days, greater physician control and improved patient experience. The platform consists of an end-to-end xCellit® workflow management and monitoring software system, a decentralized, functionally closed, automated manufacturing platform for cell therapies (using Lonza's Cocoon®) and a proprietary quality control testing and release strategy.

About Galapagos
We are a biotechnology company with operations in Europe and the U.S. dedicated to developing transformational medicines for more years of life and quality of life. Focusing on high unmet medical needs, we synergize compelling science, technology, and collaborative approaches to create a deep pipeline of best-in-class small molecules and cell therapies in oncology and immunology. With capabilities from lab to patient, including a decentralized cell therapy manufacturing network, we are committed to challenging the status quo and delivering results for our patients, employees, and shareholders. For additional information, please visit www.glpg.com or follow us on LinkedIn or X.

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).

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Forward-looking statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These statements are often, but are not always, made through the use of words or phrases such as "anticipate," "expect," "plan," "estimate," "will," "continue," "aim," "intend," "future," "potential," "could," "indicate," "forward," as well as similar expressions. Forward-looking statements contained in this release include, but are not limited to, statements regarding Galapagos' plans, expectations and strategy with respect to the ATALANTA-1 study, and statements regarding the expected timing, design and readouts of the ATALANTA-1 study, including the expected recruitment for such trials, statements related to the IND application for the Phase 1/2 ATALANTA-1 study. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause Galapagos' actual results to be materially different from those expressed or implied by such forward-looking statements. These risks, uncertainties and other factors include, without limitation, the risk that preliminary or interim clinical results may not be replicated in ongoing or subsequent clinical trials; the risk that ongoing and future clinical studies with GLPG5101 may not be completed in the currently envisaged timelines or at all, the inherent 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 GLPG5101 due to safety, efficacy or other reasons), risks related to Galapagos' reliance on collaborations with third parties (including its collaboration partner Lonza), the risk that Galapagos' estimations regarding its GLPG5101 program and the commercial potential of GLPG5101 may be incorrect, as well as those risks and uncertainties identified in Galapagos' Annual Report on Form 20-F for the year ended 31 December 2023 filed with the U.S. Securities and Exchange Commission (SEC) and its 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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[1] Kersten, M.J., 2024. Seven-day vein-to-vein point-of-care–manufactured CD19 CAR T cells (GLPG5101) in relapsed/refractory non-Hodgkin lymphoma: Results from the Phase 1/2 ATALANTA-1 trial. *EHA Library*. Available at: https://bit.ly/3xZj9Mr [Accessed 09 July 2024].

[2] Throughout this press release, 'Dr. Paul Stoffels' should be read as 'Dr. Paul Stoffels, acting via Stoffels IMC BV'.