

Galapagos presents at EBMT-EHA annual meeting 2024

Showcases meaningful advances in decentralized CAR T-cell manufacturing and presents translational and clinical data from ongoing Phase 1/2 CD19 CAR-T studies

Mechelen, Belgium; 15 February 2024, 22:01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) to present new preliminary translational data and previously disclosed data at the European Society for Blood and Marrow Transplantation (EBMT)-European Hematology Association (EHA) 6th European CAR T-cell meeting taking place from 15–17 February 2024 in Valencia, Spain.

The preliminary translational data from its EUPLAGIA-1 Phase 1/2 study demonstrate that Galapagos’ differentiated point-of-care manufacturing platform offers the potential for a single infusion of fresh early-phenotype CD19 CAR-T cells with robust expansion and persistence in patients with relapsed/refractory chronic lymphocytic leukemia (rrCLL) and patients with Richter transformation (RT). Further, previously disclosed safety, efficacy and feasibility data from EUPLAGIA-1 and ATALANTA-1 support the potential of Galapagos’ innovative approach to CAR-T manufacturing and of the transformational impact on patients with severe hematologic cancers.

“At Galapagos, we are committed to accelerating transformative innovation to address the unmet needs of patients with advanced cancers, and the data we are presenting today demonstrates our positive momentum toward this goal,” said Dr Jeevan Shetty, M.D., Head of Clinical Development Oncology at Galapagos. “We are pleased for the opportunity to present encouraging data that supports the potential of our innovative, decentralized approach to CAR-T manufacturing and the transformational impact CAR-T treatment could have on patients with serious hematologic cancers.”

Summary of preliminary translational data from EUPLAGIA-1 with GLPG5201 (cut-off date: 6 September 2023):

Patient recruitment of the Phase 1 dose-finding part of EUPLAGIA-1 has been completed and 15 patients were enrolled (6 at dose level 1 (DL1); and 9 at dose level 2 (DL2)), all of whom were diagnosed with rrCLL and 9 with additional RT. All 15 Phase 1 batches were manufactured at the point-of-care and infused as a single fresh, fit product within a median vein-to-vein time of seven days, with 80% of patients receiving the product in seven days.

GLPG5201 final product showed an increase in early phenotypes of CD4+ and CD8+ CAR-T cells (naïve, stem cell memory (T_{N/SCM}) and central memory) compared to apheresis starting material. A robust *in vivo* expansion of GLPG5201 occurred with a median time-to-peak expansion of 14 days, regardless of dose level, and a higher exposure for patients infused with DL2 compared to DL1. GLPG5201 expansion and exposure were similar in patients with rrCLL and in patients with RT. Persisting CAR-T cells were detected up to 15 months post-infusion. Moreover, the abundance of both CD4+ and CD8+ T_{N/SCM} CAR-T cells in the final product correlated with CAR-T-cell exposure in patients.

Key data highlights accepted by EBMT-EHA:

Abstract Title	Authors/Presenter	Presentation date/time
Galapagos abstracts		
Seven-Day Vein-to-Vein Point-of-Care–Manufactured GLPG5201 Anti-CD19 CAR-T Cells Display Early Phenotype in Relapsed/Refractory Chronic	<u>Sandra Blum</u> , Claire Vennin, Esmée P. Hoefsmit, Kirsten Van Hoorde, Sergi Betriu, Leticia Alserawan, Julio Delgado, Nadia Verbruggen, Anna D.D. van Muyden,	Poster Number: AS-CART-2024-00104 Date: 15 February 2024; 8:15 pm –8:45 pm Session: PT2 (Poster Tour 2)

Lymphocytic Leukemia (rrCLL) Including Richter's Transformation (RT)	Henriëtte Rozema, Ruiz Astigarraga, Margot J. Pont	
Galapagos encore abstracts		
Seven-Day Vein-to-Vein Point-of-Care Manufactured CD19 CAR-T Cells (GLPG5101) in Relapsed/Refractory Non-Hodgkin Lymphoma (rrNHL): Results from the Phase 1 ATALANTA-1 Trial	<u>Marie José Kersten</u> , Kirsten Saevels, Sophie Servais, Yves Beguin, Joost S.P. Vermaat, Eva Santermans, Stavros Milatos, Maïke Spoon, Marte C. Liefwaard, Claire Vennin, Margot J. Pont, Anna D.D. van Muyden, Maria T. Kuipers, Sébastien Anguille	Poster Number: AS-CART-2024-00090 Date: 15 February 2024; 7:45 pm –8:15 pm Session: PT1 (Poster Tour 1)
Seven-Day Vein-to-Vein Point-of-Care–Manufactured CD19 CAR T-Cell Therapy (GLPG5201) in Relapsed/Refractory Chronic Lymphocytic Leukemia (rrCLL) Including Richter’s Transformation: Results from the Phase 1 EUPLAGIA-1 Trial	<u>Natalia Tovar</u> , Nuria Martinez-Cibrian, Julio Delgado, Sergi Betriu, Leticia Alserawan, Ana Triguero, Nadia Verbruggen, Maïke Spoon, Marte C. Liefwaard, Anna D.D. van Muyden, Valentin Ortiz-Maldonado	Oral Presentation Number: AS-CART-2024-00099 Date: 16 February 2024; 6:38 pm –6:44 pm (session runs 6:20 pm –7:15 pm) Session: BA2 (Best Abstracts 2); Auditorium 1
Phase 1/2, Multicenter, Open-Label Study to Evaluate Feasibility, Safety and Efficacy of Point-of-Care–Manufactured Anti-BCMA CAR T-Cell Therapy (GLPG5301) in Relapsed/Refractory Multiple Myeloma (rrMM)	<u>Niels W.C.J. van de Donk</u> , Sébastien Anguille, Jo Caers, Marte C. Liefwaard, Christian Jacques, Anna D.D. van Muyden	Poster Number: AS-CART-2024-00103 Date: 17 February 2024; 08:30 am–1:45 pm Session: PE17p (Poster Exhibition)

About Galapagos’ decentralized CAR-T manufacturing platform

Galapagos’ decentralized, innovative point-of-care CAR T-cell manufacturing platform offers the potential for the administration of fresh, fit cells with a vein-to-vein time of seven days, greater physician control and a significantly 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 the EUPLAGIA-1 study (EudraCT 2021-003815-25)

EUPLAGIA-1 is an ongoing Phase 1/2 open-label, multi-center study evaluating the safety, efficacy and feasibility of point-of-care manufactured GLPG5201, a CD19 CAR-T product candidate, in patients with relapsed/refractory lymphocytic leukemia (rrCLL) and small cell lymphocytic lymphoma (rrSLL), with or without Richter transformation (RT). GLPG5201 is a second generation anti-CD19/4-1BB CAR-T product candidate, administered as a single fixed intravenous dose. Patients with CD19+ rrCLL or rrSLL with ≥2 lines of prior 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 was to evaluate safety and determine the recommended dose for the Phase 2 part of the study. The dose levels that were evaluated in the Phase 1 part of the study are 35x10⁶ (DL1), and 100x10⁶ (DL2) CAR+ viable T cells. 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 (CR), duration of response, progression free survival, overall survival, safety, pharmacokinetic profile, and feasibility of point-of-care manufacturing.

About chronic lymphocytic leukemia

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. CLL affects B-cells in the blood and bone marrow.¹ RT is an uncommon clinicopathological condition observed in patients with 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 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 is the most prevalent lymphoid malignancy and is the most common adult leukemia in the US and in Europe.² The annual incidence of patients with RT has been estimated at 1,900 new patients in the US and 2,000 in the EU.³

About the ATALANTA-1 study (EudraCT 2021-003272-13)

ATALANTA-1 is an ongoing Phase 1/2, open-label, multicenter study to evaluate the safety, efficacy and feasibility of point-of-care manufactured GLPG5101, a CD19 CAR-T product candidate, in patients with relapsed/refractory non-Hodgkin's lymphoma (rrNHL). GLPG5101 is a second generation anti-CD19/4-1BB CAR-T product candidate, administered as a single fixed intravenous dose. The primary objective of the Phase 1 part of the study was to evaluate safety and to determine the recommended dose for the Phase 2 part of the study. Secondary objectives include assessment of efficacy and feasibility of near the point-of-care manufacturing of GLPG5101. The dose levels that were evaluated in Phase 1 are 50×10^6 (DL1) and 110×10^6 (DL2) and 250×10^6 (DL3) CAR+ viable T cells. The primary objective of the Phase 2 part of the study is to evaluate the Objective Response Rate (ORR) while the secondary objectives include Complete Response (CR), duration of response, progression free survival, overall survival, safety, pharmacokinetic profile, and the feasibility of point-of-care manufacturing. Each enrolled patient will be followed for 24 months.

About non-Hodgkin's lymphoma

Non-Hodgkin's lymphoma is a cancer originating from lymphocytes, a type of white blood cell which is part of the body's immune system. Non-Hodgkin's 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's 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's lymphomas diagnosed in the US. Prognosis and treatment of non-Hodgkin's lymphoma depend on the stage and type of disease.

About the PAPILIO-1 Phase 1/2 study (EU CT 2022-500782-27-00)

PAPILIO-1 is a Phase 1/2, open-label, multicenter study to evaluate the safety, efficacy and feasibility of point-of-care manufactured GLPG5301, a BCMA CAR-T product candidate, in patients with relapsed/refractory multiple myeloma (rrMM) after ≥ 2 prior lines of therapy. The primary objective of the Phase 1 part of the PAPILIO-1 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 evaluate the efficacy of GLPG5301, as measured by the Objective Response Rate (ORR). Secondary objectives for both Phase 1 and Phase 2 include further assessment of the safety of GLPG5301, additional efficacy endpoints, including assessment of Minimal Residual Disease (MRD), as well as the feasibility of point-of-care manufacture of GLPG5301 in rrMM patients. Each enrolled patient will be followed for 24 months. During Phase 1, up to 3 dose levels will be evaluated and at least 12 patients will be enrolled to establish the recommended

¹ 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.

² 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>

³ IMARC report, 2023; 2-15% of incidence per Lightning Health literature review; Sigmund AM et al. 2022; Thompson PhA et al. 2022.

Phase 2 dose. Approximately 30 additional patients will be enrolled in the Phase 2 part of the study to further evaluate the safety and efficacy of GLPG5301.

About relapsed/refractory multiple myeloma (rrMM)

Multiple myeloma (MM) is typically characterized by the neoplastic proliferation of plasma cells producing a monoclonal immunoglobulin. The plasma cells proliferate in the bone marrow and may result in extensive skeletal destruction with osteopenia, and osteolytic lesions with or without pathologic fractures. The diagnosis of MM is made when one (or more) of the following clinical presentations are present: bone pain with lytic lesions discovered on routine skeletal films or other imaging modalities, an increased total serum protein concentration with the presence of a monoclonal protein in the urine or serum, and anemia, hypercalcemia or renal failure. The patient may be either symptomatic or their disease may be discovered incidentally. Despite improvements in treatment, patients with MM ultimately relapse or become refractory to available regimens. Triple-refractory patients (refractory to CD38 monoclonal antibodies (mAbs), proteasome inhibitor (PI) and immunomodulatory drug (IMiD)), or penta-refractory patients (refractory to CD38 mAbs, 2 PIs and 2 IMiDs) have a poor prognosis and are in urgent need of novel treatment options.

About Galapagos

We are a global biotechnology company with operations in Europe and the US 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, CAR-T therapies, and biologics in oncology and immunology. With capabilities from lab to patient, including a decentralized, point-of-care CAR-T 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.glp.com or follow us on [LinkedIn](#) or [X \(formerly Twitter\)](#).

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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 preliminary, interim and topline data from the EUPLAGIA-1, ATALANTA-1 and PAPILIO-1 studies and other analyses related to CD19 CAR-T, statements related to Galapagos' plans, expectations and strategy with respect to the EUPLAGIA-1, ATALANTA-1 and PAPILIO-1 studies, and statements regarding the expected timing, design and readouts of the EUPLAGIA-1, ATALANTA-1 and PAPILIO-1 studies, including the expected recruitment for trials. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause our 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 GLPG5201 and 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 GLPG5201 and GLPG5101 due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties (including its collaboration partner Lonza) and that Galapagos' estimations regarding its GLPG5201 and GLPG5101 development programs and regarding the commercial potential of GLPG5201 and 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 2022 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.