Galapagos presents new encouraging data at ASH 2023 from ongoing CD19 CAR-T studies with GLPG5201 and GLPG5101

- **Additional safety and efficacy data further support potential of innovative, decentralized approach to CAR-T manufacturing and transformational impact on patients with severe hematologic cancers**
- **Two poster presentations include recent data updates and additional data not included in the ASH abstracts**

Galapagos to host a Key Opinion Leader (KOL) event with live webcast on Sunday, 10 December 2023 at 11:00 am PT/20:00 CET

Mechelen, Belgium; 9 December 2023, 18:00 CET; Galapagos NV (Euronext & NASDAQ: GLPG) to present additional encouraging clinical data from the ongoing Phase 1/2 CD19 CAR-T studies, EUPLAGIA-1 with GLPG5201 and ATALANTA-1 with GLPG5101, in patients with relapsed/refractory chronic lymphocytic leukemia (rrCLL), with or without Richter transformation, and non-Hodgkin lymphoma (rrNHL), during two poster sessions at the 65th American Society of Hematology (ASH) Annual Meeting taking place in San Diego, from 9-12 December.

"We are very pleased to share promising new data from our ongoing CD19 CAR-T cell therapy programs, which further highlight that treatment with both GLPG5201 and GLPG5101 has the potential to deliver clinically meaningful results in these severely compromised patient populations. We are particularly encouraged that the results suggest that a vein-to-vein time of only seven days with fresh CAR-T cells is feasible, which would address the urgent needs of cancer patients who cannot afford to wait for treatment," said Dr. Jeevan Shetty, Head of Clinical Development Oncology at Galapagos. "These results demonstrate the potential of our innovative development and manufacturing approach in CAR-T cell therapy to transform the lives of patients. This data bolsters our confidence in the GLPG5201 and GLPG5101 programs for the treatment of patients with rrCLL and rrNHL, and the potential of our CAR-T pipeline beyond these initial indications."

Galapagos has an interactive booth (#3419) at the ASH congress and will organize a *Company Showcase* in room 5 A (at the congress center, upper level) on 9 December at 11:30 am PT/22:30 CET, focusing on Galapagos' 7-day vein-to-vein, fresh-to-fresh CAR-T manufacturing model at the point-of-care. In addition, Galapagos will host a media round table on 10 December at 7:30 am PT/16:30 CET at the Hilton Gaslamp Quarter San Diego, with experts discussing innovative approaches in CAR-T treatment that have the potential to transform the lives of patients around the world, and a KOL event for analysts and investors on 10 December at 11:00 am PT/20:00 CET at the Marriott Gaslamp Quarter San Diego.

GLPG5201 in rrCLL with or without Richter transformation (RT)

Patient recruitment of the Phase 1 dose-finding part of EUPLAGIA-1 has been completed and as of 6 September 2023 (cut-off date), 15 patients (6 at dose level 1 (DL1); and 9 at dose level 2 (DL2)) were enrolled, all of whom were diagnosed with rrCLL, with 9 of 15 with RT. Efficacy data as of Day 28 are available for 14 patients; 1 patient did not yet reach the Day 28 follow-up visit at the time of the analysis. The results (cut-off date: 6 September 2023) included in the poster are summarized below:

- GLPG5201 showed an encouraging safety profile with most treatment emergent adverse events (TEAEs) of Grade 1 or 2, mostly hematological. Cytokine release syndrome (CRS) Grade 1 or 2 was observed in 47% of the patients, and no CRS Grade ≥ 3 or any immune effector cell-associated neurotoxicity syndrome (ICANS) were observed. No deaths were reported.

- Overall, 13 of 14 efficacy evaluable patients responded to treatment (Objective Response Rate (ORR) of 93%) and 8 of 14 patients achieved a Complete Response Rate (CRR of 57%). 8 of 9 patients with RT responded to treatment (ORR of 89%) and 6 of 9 RT patients achieved a Complete Response (CRR of 67 %). At time of analysis, 10 of 13 of responding patients (77%) were in ongoing response with a median follow-up of 6 months; 2 of 3 patients who progressed after an initial response had confirmed CD19-negative disease.
- On the higher dose level (DL2), 8 of 8 patients responded to treatment (ORR of 100%), 5 of 8 patients achieved a Complete Response (CRR of 63%), and 6 of 6 patients with RT responded to treatment (ORR of 100%).
- DL2 was selected as the recommended dose for the Phase 2 part of the study.
- The data suggest that Galapagos' CAR-T point-of-care manufacturing platform can deliver fresh product in a median vein-to-vein time of seven days.
- Strong and consistent *in vivo* CAR-T expansion levels and a product consisting of early phenotype T cells were observed in all doses tested.

GLPG5101 in rrNHL

To further build a robust data package, patient recruitment of the Phase 1 dose-finding part of ATALANTA-1 is ongoing. As of 1 September 2023 (cut-off date), 14 heavily pre-treated rrNHL patients with diffuse large B cell lymphoma, mantle cell lymphoma and indolent lymphoma were enrolled (7 at DL1 and 7 at DL2). In parallel, enrollment of the Phase 2 expansion study is ongoing, and the first 9 patients have been dosed. The results (cut-off date: 1 September 2023) included in the poster are summarized below:

- Phase 1 part of the study:
  - GLPG5101 showed an encouraging safety profile. Most TEAEs were Grade 1 or 2 and the majority of the few Grade ≥ 3 events hematological. No CRS Grade > 3 and no ICANS Grade ≥ 2 were observed.
  - 12 of 14 evaluable patients responded to treatment (ORR of 86%), with 11 of 14 patients achieving a Complete Response (CRR of 79%). 6 of 7 patients treated with the higher dose level (DL2) responded to treatment (ORR of 86%) and achieved a Complete Response (CRR of 86%). At the time of the analysis, 8 of 12 responding patients (67%) had an ongoing response, with a duration up to 15 months (median follow-up of 8.6 months); 2 of the 4 patients who progressed after an initial response had a CD19 positive relapse and 1 had confirmed CD19-negative disease.
- Phase 2 part of the study:
  - GLPG5101 showed an encouraging safety profile with most TEAEs of Grade 1 or 2; the majority of Grade ≥ 3 events were hematological. No CRS Grade > 2 and ICANS was seen in one patient (Grade 3).
  - 6 of 7 evaluable patients responded to treatment (ORR of 86%) and a Complete Response was observed in 4 of 7 patients (57%). At the time of the analysis, all 6 responding patients (100%) had an ongoing response with a median follow-up of 3.2 months.
- The data suggest that Galapagos' point-of-care platform can deliver fresh product in a median vein-to-vein time of seven days.
- Strong and consistent *in vivo* CAR-T expansion levels and a product consisting of early phenotype T cells were observed in all doses tested.

Natalia Tovar, MD, PhD, Hospital Clinic de Barcelona, *Institut d'Investigacions Biomèdiques* August Pi I Sunyer (IDIBAPS), University of Barcelona (Spain) presented the analysis on the Phase 1 part EUPLAGIA-1 in patients with rrCLL, with or without RT. Marie José Kersten, MD, PhD, Professor of Hematology and Head of the Department of Hematology at the Academic Center in Amsterdam (The Netherlands) presented the analysis on the Phase 1 and Phase 2 parts of ATALANTA-1 in patients with rrNHL.

The poster presentations are available in the poster hall and the ASH website:

Abstract Title	Authors	Presentation details
Seven-day Vein-to-Vein Point-of-Care Manufactured CD19 CAR T Cells (GLPG5201) in Relapsed/Refractory CLL/SLL including Richter's Transformation: Results from the Phase 1 Euplagia-1 Trial	Natalia Tovar, Valentin Ortiz-Maldonado, Nuria Martinez-Cibrian, Sergi Betriu, Daniel Esteban, Ana Triguero, Nadia Verbruggen, Anna D.D. van Muyden, Maike Spoon, Margot J. Pont	Abstract Poster Number: 2112 Date: 9 Dec, 5:30–7:30 pm PT Session: Cellular Immunotherapies: Early Phase and Investigational Therapies: Poster I
Seven-day Vein-to-Vein Point-of-Care Manufactured CD19 CAR T Cells (GLPG5101) in Relapsed/Refractory NHL: Results from the Phase 1 Atalanta-1 Trial	Marie José Kersten, Kirsten Saevels, Sophie Servais, Yves Beguin, Joost Vermaat, Nadia Verbruggen, Anna DD Van Muyden, Margot J Pont, Maria T Kuipers, Sébastien Anguille	Abstract Poster Number: 2113 Date: 9 Dec, 2023, 5:30–7:30 pm PT Session: Cellular Immunotherapies: Early Phase and Investigational Therapies: Poster I

About Galapagos' innovative approach to CAR-T manufacturing near the point-of-care

Galapagos' decentralized, innovative point-of-care CAR-T manufacturing platform consists of a proprietary 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 (QC) testing and release strategy. The combination of these three core components allows for the administration of a fresh product, a median vein-to-vein time of seven days (i.e. the time between T-cell collection and CAR-T infusion), and greater physicians oversight throughout the process.

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 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 intravenous infusion of a fresh product candidate in a single fixed 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 $35x10^6$ (DL1), and $100x10^6$ (DL2) CAR+ viable T cells.

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

[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.

incidence of 4.7 new cases per 100,000 individuals, CLL is the most prevalent lymphoid malignancy and is the most common adult leukemias in the US and in Europe.[2]

About the ATALANTA-1 study (EudraCT 2021-003272-13)
ATALANTA-1 is an ongoing Phase 1/2, open-label, multicenter study to evaluate the feasibility, safety, and efficacy 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 an intravenous infusion of a fresh product candidate in a single fixed dose. Each enrolled patient will be followed for 24 months. 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 point-of-care manufacturing of GLPG5101. The dose levels that were evaluated in Phase 1 are $50x10^6$ (DL1) and $110x10^6$ (DL2) and $250x10^6$ (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 rate (CRR), duration of response, progression free survival, overall survival, safety, pharmacokinetic profile, and feasibility of point-of-care manufacturing.

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 lymphomas depend on the stage and type of disease.

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 the most 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.glpg.com or follow us on LinkedIn or X (formerly Twitter).

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[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

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 and ATALANTA-1 studies and other analyses related to CD19 CAR-T, statements related to Galapagos' plans, expectations and strategy with respect to the EUPLAGIA-1 and ATALANTA-1 studies, and statements regarding the expected timing, design and readouts of the EUPLAGIA-1 and ATALANTA-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.