

Galapagos showcases innovative approach in hematological cancer care with clinical and translational data presentations at EBMT congress 2024

Two oral presentations and one poster on encore preliminary data from Phase 1/2 CD19 CAR-T studies in non-Hodgkin lymphoma (NHL) and chronic lymphocytic leukemia (CLL) / Richter transformation (RT)

Mechelen, Belgium; 4 April 2024, 22:01 CET – Galapagos NV (Euronext & NASDAQ: GLPG) today announced that four abstracts, including two oral presentations on encore preliminary clinical and translational data for its seven-day vein-to-vein CAR-T product candidates GLPG5101 and GLPG5201, will be presented at the 50th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT) to be held in Glasgow, UK, on 14-17 April 2024.

ATALANTA-1 and EUPLAGIA-1 are ongoing Phase 1/2 open-label, multi-center studies designed to assess the safety, efficacy and feasibility of point-of-care manufactured GLPG5101 and GLPG5201 in patients with relapsed/refractory NHL, and relapsed/refractory CLL and RT, respectively. The primary objective of the Phase 1 part of the studies is to evaluate the safety and preliminary efficacy to determine the recommended dose for the Phase 2 part of the study. The primary objective of the Phase 2 part of the studies 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. GLPG5101 and GLPG5201 are second generation anti-CD19/4-1BB CAR-T product candidates, administered as a single fixed intravenous dose.

“We are committed to accelerating breakthrough innovations to extend the reach of CAR-T therapies to patients with rapidly progressing cancers,” said Dr. Jeevan Shetty, M.D., Head of Clinical Development Oncology at Galapagos. “We believe that the preliminary safety and efficacy data from our ongoing Phase 1/2 studies with our CD19 CAR-T therapy candidates in patients with relapsed/refractory NHL, CLL and RT, combined with our unique, innovative decentralized manufacturing approach that enables a seven-day vein-to-vein time, support the promise of GLPG5101 and GLPG5201 in addressing the critical needs of patients facing poor prognosis.”

The following table provides a summary of Galapagos’ presentations at EBMT 2024:

Abstract Title	Authors/Presenter	Presentation date/time
Galapagos encore abstracts		
Seven-Day Vein-to-Vein Point-of-Care Manufactured CD19 CAR T-Cell Therapy (GLPG5101) in Relapsed/Refractory Non-Hodgkin Lymphoma (NHL): Results from the Phase 1 ATALANTA-1 Trial	Marie José Kersten, Kirsten Saevens, Sophie Servais, Yves Beguin, Joost S.P. Vermaat, Eva Santermans, Stavros Milatos, Maike Spoon, Marte C. Liefwaard, Claire Vennin, Margot J. Pont, Anna D.D. van Muyden, Maria T. Kuipers , Sébastien Anguille	Oral presentation number: OS16-04 Date: 17 April, 12:57-13:06 (session runs 12:30-13:45) Session: Oral Session 16: CAR-T outcomes in ALL
Seven-Day Vein-to-Vein Point-of-Care–Manufactured CD19 CAR T-Cell Therapy (GLPG5201) in Relapsed/Refractory Chronic Lymphocytic Leukemia Including Richter Transformation: Results from the Phase 1 EUPLAGIA-1 Study	Valentin Ortiz-Maldonado , Nuria Martinez-Cibrian, Julio Delgado, Sergi Betriu, Leticia Alserawan, Ana Triguero, Nadia Verbruggen, Maike Spoon, Marte C. Liefwaard, Anna D.D. van Muyden, Natalia Tovar	Oral presentation number: OS16-05 Date: 17 April, 13:06-13:15 (session runs 12:30-13:45) Session: Oral Session 16: CAR-T outcomes in ALL
EUPLAGIA-1: Seven-Day Vein-to-Vein Point-of-Care Manufactured GLPG5201	Esmée P. Hoefsmit , Sandra Blum, Claire Vennin, Kirsten Van Hoorde, Sergi Betriu,	Poster number: A073 Date: 15 April, 18:00-19:00

Anti-CD19 CAR-T Cells Display Early Phenotypes in Relapsed/Refractory CLL, including RT	Leticia Alserawan, Julio Delgado, Nadia Verbruggen, Anna D.D. van Muyden, Henriëtte Rozema, Ruiz Astigarraga, Margot J. Pont	Session: Printed poster: CAR-based Cellular Therapy - Clinical
PAPILIO-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	Niels W.C.J. van de Donk, Sébastien Anguille, Jo Caers, Marte C. Liefwaard, Christian Jacques, Anna D.D. van Muyden	Poster number: P049 Date: 14 April, 08:30-18:00 Session: ePoster: CAR-based Cellular Therapy - Clinical

About Galapagos’ decentralized CAR-T manufacturing platform

Galapagos’ decentralized, innovative CAR T-cell manufacturing platform near the point-of-care 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 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 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 is to evaluate the safety and preliminary efficacy 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 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 chronic 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 is to evaluate the safety and preliminary efficacy to 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 35×10^6 (DL1) and 100×10^6 (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 Galapagos

We are a 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 and ATALANTA-1 studies and other analyses related to Galapagos' CD19 CAR-T program, 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 such trials. 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 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.