Galapagos Presented New Data at ICML 2025 From Cohort 3 of ATALANTA-1 in Relapsed/Refractory Indolent NHL Patients, Demonstrating High Complete Response and MRD Negativity Rates With CAR-T Candidate GLPG5101

Of the 34 patients enrolled in Cohort 3 of the ATALANTA-1 Phase 1/2 study, 32 received GLPG5101; 94% were infused with fresh CAR-T cells, and 93% were treated within seven days of manufacturing

GLPG5101 demonstrated promising efficacy with durable CAR-T cell persistence and a favorable safety profile, including a 97% complete response rate, 100% MRD negativity in evaluable patients, sustained CAR-T expansion up to 21 months, and low rates of severe CRS and ICANS, with no deaths reported

Mechelen, Belgium; June 18, 2025, 22:01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) today presented new data from the ongoing ATALANTA-1 Phase 1/2 study of its investigational CD19 CAR T-cell therapy, GLPG5101, in an oral presentation at the 18th International Conference on Malignant Lymphoma (ICML). These data demonstrate high complete response (CR) and minimal residual disease (MRD) rates in heavily pretreated relapsed/refractory indolent non-Hodgkin lymphoma (R/R iNHL) patients (ATALANTA-1 Cohort 3). Additionally, with a rapid vein-to-vein time enabled by Galapagos' decentralized manufacturing platform, 93% of patients treated in the study received fresh, non-cryopreserved GLPG5101, without the need for cytotoxic bridging therapy.

"These safety, efficacy and manufacturing results represent a significant milestone for our GLPG5101 program in relapsed/refractory B-cell malignancies," said Omotayo Fasan, M.D., Clinical Development Program Head at Galapagos. "For patients who have often exhausted multiple lines of therapy and face limited treatment options, the favorable safety profile, high complete response rate, and consistent minimal residual disease negativity we observed are especially encouraging."

"I am encouraged by the 97% progression free survival rate at 12 months and the favorable safety profile of GLPG5101, as well as the enrichment of early phenotype cells in the final product," said Maria Kuipers, M.D., of the Department of Hematology at the Academic Center in Amsterdam (The Netherlands). "The ability to deliver a fresh, early-memory-enriched CAR T-cell product within seven days of leukapheresis without the need for cytotoxic bridging therapy is a promising advancement for the field. This turnaround not only helps mitigate the risk of disease progression during the waiting period, but also spares patients from additional chemotherapy and its associated toxicities. Together, these findings highlight the promise of decentralized CAR-T manufacturing in enabling timely, scalable, and personalized cell therapies "

The new ATALANTA-1 data for the completely enrolled Cohort 3 are summarized below:

The oral presentation at ICML features new safety, efficacy and manufacturing data for GLPG5101 from the completely enrolled cohort in R/R indolent NHL (Cohort 3) of the ongoing ATALANTA-1 Phase 1/2 study. As of the October 14, 2024 data cut-off, 34 patients with R/R iNHL (follicular lymphoma, FL, n=29); (marginal zone lymphoma, MZL, n=5) underwent leukapheresis, of whom 32 (94%) received an infusion of GLPG5101.

- Of those 32 patients:
  - 94% (30 patients) received a fresh product.
  - 93% (28 patients) received it with a 7-day vein-to-vein time, avoiding the need for cytotoxic bridging therapy.
  - 6% (2 patients) received a cryopreserved product with a 13-day vein-to-vein time.
- The proportion of early phenotype $CD4^+$ and $CD8^+$ CAR-T cells increased significantly in the final product versus starting material.

- GLPG5101 showed a promising efficacy profile with robust and durable CAR-T cell expansion:
  - At month 9, 100% of evaluable patients (13/13) had persisting CAR-T cells and CAR-T cells were detected up to 21 months.
  - A complete response (CR) rate of 97% was observed with 31/32 infused patients responding to treatment and 100% of evaluable patients (10/10) being MRD negative at time of CR.
  - The 12-month progression free survival (PFS) rate was 97%, with no reported relapses.
- GLPG5101 showed a favorable safety profile:
  - The majority of Grade ≥ 3 treatment emergent adverse events were hematological.
  - Cases of cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) were few and predominantly low-grade with only a single Grade 3 report of ICANS.
  - There were no deaths reported.

	ORR (%)	CRR (%)	CR (n/N)	No response (n/N)
FL (n=27)	96%	96%	26/27	1/27
MZ (n=5)	100%	100%	5/5	0/5
All iNHL (n=32)	97%	97%	31/32	1/32

Table 1: Objective and complete response rates (all GLPG5101 infused patients)

About GLPG5101 and ATALANTA-1 (EudraCT 2021-003272-13; NCT 06561425)

GLPG5101 is a second generation anti-CD19/4-1BB CAR-T product candidate, administered as a single fixed intravenous dose. The safety, efficacy and feasibility of decentralized manufactured GLPG5101 are currently being evaluated in the ATALANTA-1 Phase 1/2 study in eight[1] hematological malignancies with high unmet need. The primary objective of the Phase 1 part of the study is 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 decentralized manufacturing of GLPG5101. The dose levels that were evaluated in Phase 1 are $50x10^6$ (DL1), $110x10^6$ (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 the feasibility of decentralized manufacturing. Each enrolled patient will be followed for 24 months. The ATALANTA-1 study is currently enrolling patients in the U.S. and Europe.

About Galapagos' cell therapy manufacturing platform

Galapagos' innovative decentralized cell therapy manufacturing platform is designed to enable the administration of fresh, fit, stem-like early memory cells with a median vein-to-vein time of seven days, greater physician visibility, 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

Galapagos is a biotechnology company with operations in Europe, the U.S., and Asia, dedicated to transforming patient outcomes through life-changing science and innovation 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 medicines. With capabilities from lab to patient, including a decentralized cell therapy manufacturing platform, we are committed to

[1] Protocol for GLPG5101 currently being amended to include chronic lymphocytic leukemia.

challenging the status quo and delivering results for our patients, employees, and shareholders. Our goal is to meet current medical needs and anticipate and shape the future of healthcare, ensuring that our innovations reach those who need them most. For additional information, please visit www.glpg.com or follow us on LinkedIn or X.

For further information, please contact:

Media inquiries:
Marieke Vermeersch
+32 479 490 603
media@glpg.com

Investor inquiries:
Glenn Schulman
+1 412 522 6239
ir@glpg.com

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," "will," "continue," "aim," "future," "potential," "forward," "may," as well as similar expressions. Forward-looking statements contained in this press release include, but are not limited to, statements regarding new data from the ATALANTA-1 Phase 1/2 study, statements regarding the expected timing, design and readouts of the ATALANTA-1 study, statements regarding Galapagos' cell therapy manufacturing platform, and statements regarding the potential benefits of GLPG5101. 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 Galapagos' product candidates, including 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), Galapagos' reliance on collaborations with third parties (including its collaboration partner Lonza), and that Galapagos' estimations regarding its GLPG5101 development program and regarding 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 2024 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, unless specifically required by law or regulation.