Galapagos to Present New ATALANTA-1 CAR-T Data at EHA 2025, Highlighting Low Toxicity and Rapid, Decentralized Delivery of Fresh, Early-Memory-Enriched GLPG5101 in R/R NHL

Data reported from the ongoing ATALANTA-1 Phase 1/2 study in a heavily pretreated relapsed refractory non-Hodgkin's Lymphoma (R/R NHL) patient population demonstrate low rates of high-grade toxicities

Of the 64 patients enrolled, 61 received treatment, resulting in a 5% attrition rate, significantly lower than industry benchmarks. 95% of patients were infused with fresh, stem-like early memory CD19 CAR-T cells, with 89% receiving treatment within 7 days, avoiding the need for cryopreservation and cytotoxic bridging therapy

Mechelen, Belgium; June 12, 2025, 22:01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) will present 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 30th European Hematology Association (EHA) Congress. These data demonstrate encouraging safety outcomes, including low rates of high-grade toxicities, in R/R NHL. Additionally, with a rapid vein-to-vein time enabled by Galapagos' decentralized manufacturing platform, 95% of patients treated in the study received fresh, non-cryopreserved GLPG5101, without the need for cytotoxic bridging therapy.

"We are excited to share new promising safety and manufacturing data for GLPG5101 across multiple R/R NHL subtypes, reinforcing the potential of our novel rapid delivery approach," said Omotayo Fasan, M.D., Clinical Development Program Head at Galapagos. "By initiating lymphodepletion immediately after cell collection, we are able to infuse fresh product as soon as it becomes available, reducing patient attrition and potentially expanding access to CAR-T therapy. We observed a low 5% attrition rate, compared to rates of up to 30% reported in some clinical trials and real-world settings, and observed a manageable safety profile. These promising results suggest that rapid delivery of fresh, stem-like early memory cell therapies may offer meaningful clinical benefits for patients with R/R NHL."

"Decentralized cell therapy manufacturing is changing how we think about CAR-T eligibility. By enabling shorter vein-to-vein times and the use of fresh, early memory phenotype cells, this approach may allow for the inclusion of patients who would otherwise not be able to receive CAR-T therapy due to historically long manufacturing timelines," said Pim Mutsaers, M.D., Associate Professor, Department of Hematology, Erasmus MC Cancer Institute.

The new ATALANTA-1 data are summarized below:

The oral presentation at EHA features new safety and longer follow-up data for GLPG5101 in 64 patients with R/R large B-cell lymphoma (DLBCL, n=17), mantle cell lymphoma (MCL, n=13), follicular lymphoma (FL, n=29), and marginal zone lymphoma (MZL, n=5) from the ongoing ATALANTA-1 Phase 1/2 study (data cut-off: October 14, 2024). The presentation also demonstrates the feasibility of Galapagos' decentralized manufacturing platform to deliver fresh, stem-like early memory cell therapy with a median vein-to-vein time of seven days, robust *in vivo* expansion, and durable persistence.

- As of 14 October 2024, 64 patients underwent leukapheresis, of whom 63 received lymphodepleting chemotherapy and 61 (95%) received an infusion of GLPG5101. Of those 61 patients:
  - 95% (58 patients) received a fresh product
  - 89% (54 patients) received it within 7 days post-leukapheresis
  - 7% (4 patients) received it within 8-21 days

  - 5% (3 patients) received a cryopreserved product
- None of the patients who received a fresh product required cytotoxic bridging therapy.
- GLPG5101 showed an encouraging safety profile in the context of robust CAR T-cell peak expansion and durable persistence, with the majority of Grade ≥ 3 treatment emergent adverse events being hematological. Cases of CRS and ICANS were few and predominantly low-grade with only a single Grade 3 report of each. Dose-limiting toxicities were found in 8% of patients (5/61).
- Durable CAR T-cell persistence was observed up to 21 months across tumor types, phases, and dose levels.

	Phase 1 (n=24)	Phase 2 (n=37)	All patients (n=61)
CRS, n (%)	**11 (45.8)**	**15 (40.5)**	**26 (42.6)**
Grade 1, n (%)	5 (20.8)	8 (21.6)	13 (21.3)
Grade 2, n (%)	5 (20.8)	7 (18.9)	12 (19.7)
Grade 3, n (%)	1 (4.2)	0	1 (1.6)
Time to onset, median (range), days	7.5 (2–20)	7.0 (1–11)	7.0 (1–20)
Duration, median (range), days	3.0 (1–17)	3.0 (1–9)	3.0 (1–17)
CRS toxicity management, n (%)			
Dexamethasone	4 (16.7)	7 (18.9)	11 (18.0)
Tocilizumab	6 (25.0)	9 (24.3)	15 (24.6)
Methylprednisolone	1 (4.2)	-	1 (1.6)
Vasopressin	1 (4.2)	-	1 (1.6)
ICANS, n (%)	**8 (33.3)**	**4 (10.8)**	**12 (19.7)**
Grade 1	8 (33.3)	3 (8.1)	11 (18.0)
Grade 2	0	0	0
Grade 3	0	1 (2.7)	1 (1.6)
Time to onset, median (range), days	14.0 (3–30)	8.5 (2–12)	11.5 (2–30)
Duration, median (range), days	2.5 (1–47)	1.5 (1–3)	2.0 (1–47)
ICANS toxicity management, n (%)			
Dexamethasone (ICANS)	2 (8.3)	4 (10.8)	6 (9.8)
Tocilizumab (ICANS)	1 (4.2)	2 (5.4)	3 (4.9)
Infections, Grade ≥3, n (%)	**2 (8.3)**	**1 (2.7)**	**3 (4.9)**
Hemophagocytic lymphohistiocytosis, Grade ≥3, n (%)	**2 (8.3)**	**0**	**2 (3.3)**
Prolonged cytopenias,[a] Grade ≥3, n/n available (%)			
30 days after infusion	8/21 (38.1)	11/37 (29.7)	19/58 (32.8)
60 days after infusion	5/21 (23.8)	9/33 (27.3)	14/54 (25.9)
90 days after infusion	4/20 (20.0)	8/30 (26.7)	12/50 (24.0)

[a] Includes all events related to neutropenia, thrombocytopenia, anemia, and lymphopenia.
CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome.

Table 1: Adverse events of special interest

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.

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

About Galapagos' cell therapy manufacturing platform

Galapagos' innovative decentralized cell therapy manufacturing platform has the potential for 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 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.

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