

Galapagos Presented New ATALANTA-1 Cell Therapy Data in MCL at ASH 2025

High complete response rates and minimal residual disease (MRD) negativity, with durable responses, in high-risk mantle cell lymphoma (MCL) with GLPG5101, a fresh, early memory-enriched CAR T-cell therapy with a 7-day vein-to-vein time

Mechelen, Belgium; December 8, 2025, 07:30 CET; Galapagos NV (Euronext & NASDAQ: GLPG) announced new and updated Phase 2 data from the ongoing ATALANTA-1 study with its CD19 CAR T-cell therapy candidate, GLPG5101, during an oral presentation (#662) at the 67th American Society of Hematology (ASH) Annual Meeting.

“The new and updated results from the Phase 2 ATALANTA-1 study demonstrate that GLPG5101 offers timely treatment with low rates of high-grade toxicities and durable responses for patients with relapsed or refractory MCL,” said Marie José Kersten, MD, ATALANTA-1 Principal Investigator and Professor of Hematology at Amsterdam University Medical Center. “The short 7-day vein-to-vein time enabled a low dropout rate and eliminated the need for bridging therapy, allowing more patients to receive treatment who otherwise might not have been able to access CAR T-cell therapy.”

Summary of ATALANTA-1 data from the MCL cohort (pooled data across two dose levels):

As of September 2, 2025 (data cut-off date), 26 heavily pretreated MCL patients had undergone leukapheresis and 25 had received an infusion of GLPG5101 (4% dropout rate). Of these, 24 patients received a fresh product, with 23 infused within seven days after apheresis.

- Among infused patients (N=24), the objective response rate (ORR) was 100%, with a complete response rate (CRR) of 96%. Duration of response (DOR) and progression-free survival (PFS) rates were both 83% at a median follow-up of 9 months.
- 9 of 10 (90%) of minimal residual disease (MRD)-evaluable patients were MRD-negative at CR and 7 of 9 MRD-negative patients remained in CR at the time of the data cut-off.
- GLPG5101 showed an encouraging safety profile (N=24). The most common Grade \geq 3 treatment-emergent adverse events were hematologic. No Grade \geq 3 CRS was observed, and only one case of Grade \geq 3 ICANS occurred.
- GLPG5101 demonstrated robust *in vivo* CAR T-cell expansion and long-term persistence with an enrichment of early memory phenotypes.

Intention to wind down Galapagos' cell therapy activities

As announced on [October 21, 2025](#), and following a comprehensive strategic and evaluation and sales process, Galapagos remains focused on the intention to wind down the cell therapy activities. This intention is subject to the conclusion of consultations with works councils in Belgium and the Netherlands, during which Galapagos will continue to operate the business and conduct ongoing clinical studies. Galapagos would still consider any viable proposal to acquire all, or part of the cell therapy business, should such a proposal emerge during the wind down process.

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 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 50×10^6 (DL1), 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 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.

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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,” “may,” as well as similar expressions. Forward-looking statements contained in this press release include, but are not limited to, statements regarding Galapagos’ plans, expectations and strategy with respect to its cell therapy business, including statements regarding its plans, expectations and strategy for GLPG5101 and its other product candidates and partnered programs, Galapagos’ intention to wind down its cell therapy business as part of its ongoing transformation, the expected timing, design and readouts of the ATALANTA-1 study, and the potential benefits of Galapagos’ product candidates. 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 Galapagos will not be able to successfully implement the winding down of its cell therapy business within the expected timeframe or at all, or if implemented, the wind down will not achieve its anticipated economic benefits; 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 partners Lonza and US WorldMeds), and that Galapagos’ estimations regarding its GLPG5101 development programs 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. Further, Galapagos cannot assess the impact of each such factor on its business or the extent to which any factor, or combination of factors, may cause actual results to be materially different from those contained in any forward-looking statement.