

## **Galapagos Announces Encouraging New Results from Ongoing Phase 1/2 Study of CD19 CAR T-Cell Therapy, GLPG5101, in Patients with Relapsed/Refractory Non-Hodgkin Lymphoma**

- Data from the ongoing Phase 1/2 ATALANTA-1 study in a heavily pretreated R/R NHL patient population demonstrate high antitumor activity and an encouraging safety profile in all NHL subtypes studied.
- 96% of patients received an infusion of fresh, fit, stem-like, early memory CD19 CAR T-cell therapy with a median vein-to-vein time of seven days, avoiding the need for cryopreservation and bridging therapy.
- These data reinforce the potential of Galapagos' decentralized cell therapy manufacturing platform to deliver fresh, fit cells, fast, driving positive patient outcomes.

Mechelen, Belgium; December 7, 2024, 18:30 CET; Galapagos NV (Euronext & NASDAQ: GLPG) today announced additional data from the ongoing Phase 1/2 ATALANTA-1 study of its CD19 CAR T-cell therapy, GLPG5101. The results, featured in an oral presentation at the 66<sup>th</sup> American Society of Hematology (ASH) Annual Meeting and Exposition, demonstrate an encouraging efficacy and safety profile in patients with relapsed/refractory non-Hodgkin lymphoma (R/R NHL). Most patients in the study received GLPG5101 as a fresh, fit, stem-like, early memory CD19 CAR T-cell therapy, with a median vein-to-vein time of seven days.

“Shorter vein-to-vein time can lead to improved patient outcomes and remains an important unmet need in CAR-T therapy,” said Marie José Kersten, MD, ATALANTA-1 Principal Investigator and Professor of Hematology at the Department of Hematology at Amsterdam University Medical Center. “I am impressed by the latest data on GLPG5101, which demonstrate a promising efficacy and safety profile. With a median vein-to-vein time of just seven days, GLPG5101 has the potential to offer speed and scheduling flexibility, comparable to off-the-shelf therapies.”

“CAR-T therapies are highly personalized treatments that currently undergo a time-intensive manufacturing process taking multiple weeks to months. For many patients with rapidly progressing cancers, every day counts, and treatment delays can be detrimental,” said Jeevan Shetty, MD, Head of Clinical Development Oncology at Galapagos. “We are steadfast in our commitment to bring innovation to cell therapies to address the most significant medical challenges. Our latest data at ASH strongly support the feasibility of our innovative decentralized cell therapy manufacturing platform in delivering fresh, fit cells with a median vein-to-vein time of just seven days, driving positive patient outcomes.”

### **The new ATALANTA-1 data are summarized below:**

The ongoing ATALANTA-1 study included updated data on patients with mantle cell lymphoma (MCL), marginal zone lymphoma (MZL), follicular lymphoma (FL), and diffuse large B-cell lymphoma (DLBCL). As of the April 25, 2024, data cut-off, 49 patients received CD19 CAR T-cell therapy infusion, and safety and efficacy results were available for 45 patients and 42 patients, respectively.

- High objective response rates (ORR) and complete response rates (CRR) were observed in the pooled Phase 1 and Phase 2 efficacy analysis set, split by indication:
  - In patients with MCL, all 8 of 8 efficacy-evaluable patients responded to treatment (ORR and CRR 100%).
  - In patients with MZL, FL, objective and complete responses were observed in 20 of 21 efficacy-evaluable patients (ORR and CRR 95%).

- In patients with DLBCL, 9 of 13 efficacy-evaluable patients responded to treatment (ORR 69%), with 7 patients achieving a complete response (CRR 54%). Of the 7 patients with DLBCL who received the higher dose, 6 responded to treatment (ORR 86%) with 5 achieving a complete response (CRR 71%).
- Of the 15 minimal residual disease (MRD)-evaluable patients with a complete response, 12 patients (80%) achieved MRD negativity and remained in complete response at data cut-off.
- The median study follow-up was 3.3 months for FL and DLBCL with a range of 0.9-21.2 months, and 4.4 months for MCL with a range of 1-24.4 months.
- GLPG5101 showed an encouraging safety profile, with the majority of Grade  $\geq 3$  treatment emergent adverse events being hematological. One case of CRS Grade 3 was observed in Phase 1 and one case of ICANS Grade 3 was observed in Phase 2.
- 96% of patients (47 of 49) received an infusion with fresh, fit, stem-like early memory CD19 CAR T-cell therapy, with 91.5% (43 of 47) achieving a vein-to-vein time of seven days, thereby avoiding cryopreservation, and eliminating the need for bridging therapy.
- Strong and consistent *in vivo* CAR-T expansion levels and products consisting of stem-like, early memory phenotype T cells were observed in all doses tested.

#### **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 decentralized manufactured GLPG5101, a CD19 CAR-T product candidate, in patients with relapsed/refractory non-Hodgkin lymphoma (R/R NHL). 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 decentralized manufacturing of GLPG5101. The dose levels that were evaluated in Phase 1 are  $50 \times 10^6$  (DL1),  $110 \times 10^6$  (DL2) and  $250 \times 10^6$  (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.

#### **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 T-cells within 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<sup>®</sup> workflow management and monitoring software system, a decentralized, functionally closed, automated manufacturing platform for cell therapies (using Lonza's Cocoon<sup>®</sup>) and a proprietary quality control testing and release strategy.

#### **About Galapagos**

We are a biotechnology company with operations in Europe and the U.S. 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 small molecules and cell therapies in oncology and immunology. With capabilities from lab to patient, including a decentralized cell therapy manufacturing platform, and the financial strength to invest strategically for the near- and long-term, we are committed to challenging the status quo and delivering results for our patients, employees, and shareholders. Our

goal is not just to meet current medical needs but to anticipate and shape the future of healthcare, ensuring that our innovations reach those who need them most. For additional information, please visit [www.glpj.com](http://www.glpj.com) or follow us on [LinkedIn](#) or [X](#).

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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 preliminary, interim and topline data from the ATALANTA-1 study and other analyses related to Galapagos’ CD19 CAR-T programs, statements related to Galapagos’ plans, expectations and strategy with respect to the ATALANTA-1 study, and statements regarding the expected timing, design and readouts of the ATALANTA-1 study, including the expected recruitment for such studies, and the potential benefits of Galapagos’ product candidates, including GLPG5101, and partnered programs, including uza-cel. 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 studies, 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 study 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 Adaptimmune), 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 December 31, 2023 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.*