Galapagos presents encouraging new data for CD19 CAR-T candidate GLPG5101 in non-Hodgkin lymphoma at EHA 2024

Mechelen, Belgium; June 14, 2024, 22:01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) today announced that it will present encouraging new data from the ongoing Phase 1/2 ATALANTA-1 study of CD19 CAR-T candidate, GLPG5101, in relapsed/refractory non-Hodgkin lymphoma (R/R NHL) at the annual European Hematology Association (EHA) 2024 Hybrid Congress. Galapagos' product candidate GLPG5101 is produced using the company's innovative, decentralized T-cell manufacturing platform.

The oral presentation includes updated safety and efficacy data for GLPG5101 in patients with diffuse large B-cell lymphoma (DLBCL), follicular lymphoma (FL), marginal zone lymphoma (MZL) and mantle cell lymphoma (MCL). The presentation also includes durability and cellular kinetics data. At the data cut-off date of December 20, 2023, no unexpected safety findings were observed and treatment with GLPG5101 resulted in high complete response rates in all indications in this heavily pretreated patient population.

GLPG5101 was administered as a fresh product in 94% of patients with a median vein-to-vein time of seven days, eliminating the need for bridging therapy. T-cell subsets were assessed in the apheresis starting material and final CAR-T product. There was a higher proportion of early phenotypes of CD4+ and CD8+ CAR T cells (naive/stem cell memory and central memory T cells) in the final product compared with starting material, indicating an increase of those populations during the manufacturing process. This demonstrates the feasibility of Galapagos' decentralized manufacturing platform to deliver a high-quality CAR T-cell product to patients.

The new data will be presented by Marie José Kersten, M.D., Professor of Hematology and Head of the Department of Hematology at the Amsterdam University Medical Center.

"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 are delighted to present promising new data for GLPG5101 at the EHA congress. The high complete response rates, combined with low-grade CRS and ICANS, demonstrates the potential of GLPG5101 in addressing the critical needs of this patient population. The data also confirm the feasibility of our innovative decentralized T-cell manufacturing platform in delivering fresh, fit cells with a median vein-to-vein time of just seven days."

Key new data from the ongoing Phase 1/2 ATALANTA-1 study include:
As of the data cut-off date of December 20, 2023, 34 patients (17 in Phase 1 and 17 in Phase 2) received GLPG5101 with a median vein-to-vein time of seven days. Overall, safety results were available for 33 patients and efficacy results were available for 31 patients. The data are summarized below:

- GLPG5101 showed an encouraging safety profile with most TEAEs[1] of Grade 1 or 2; the majority of Grade ≥ 3 events were hematological. Two cases of CRS[2] Grade 3 were observed in Phase 1 and one case of ICANS[3] Grade 3 was observed in Phase 2.
- In Phase 1, 14 of 16 efficacy-evaluable patients responded to treatment (objective response rate, ORR 87.5%), with 12 patients achieving a complete response (CR) (CR rate, CRR 75%). In Phase 2, 14 of 15 efficacy-evaluable patients responded to treatment (ORR 93.3%), and all responders achieved a complete response (CRR 93.3%).

[1] *Treatment Emergent Adverse Events*
[2] *Cytokine Release Syndrome*
[3] *Immune effector Cell-Associated Neurotoxicity Syndrome*

- High ORR and CRR were observed in the pooled Phase 1 and Phase 2 efficacy analysis set, split by indication:
  - In patients with DLBCL, 7 of 9 efficacy-evaluable patients responded to treatment (ORR 78%), with 5 patients achieving a complete response (CRR 56%).
  - In patients with FL or MZL, objective and complete responses were observed in 16 of 17 efficacy-evaluable patients (ORR and CRR 94%).
  - In patients with MCL, all 5 of 5 efficacy-evaluable patients responded to treatment (ORR and CRR 100%).
- Durable responses were observed in the majority of responding patients:
  - 71% of patients in Phase 1 had an ongoing response at data cut-off with median follow-up of 13.1 months.
  - 100% of patients in Phase 2 had an ongoing response at data cut-off with median follow-up of 4.2 months.
- Strong and consistent *in vivo* CAR-T expansion levels and products consisting of early phenotype T cells were observed in all doses tested.

Presentation details:

Abstract number/title	Authors/Presenter	Presentation date/time
Abstract #S243 Seven-Day Vein-to-Vein Point-of-Care Manufactured CD19 CAR T Cells (GLPG5101) in Relapsed/Refractory Non-Hodgkin Lymphoma: Results from the Phase 1/2 Atalanta-1 Trial	Marie José Kersten, Kirsten Saevels, Sophie Servais, Evelyne Willems, Marte C. Liefaard, Stavros Milatos, Margot J. Pont, Claire Vennin, Eva Santermans, Anna D.D. Van Muyden, Maria T. Kuipers, Sébastien Anguille, Joost S.P. Vermaat	Saturday, June, 15 12:15- 12:30 pm CET Session s422: Aggressive lymphoma – CAR-T cell therapy Hall Dali 2

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 near the point-of-care 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.

About non-Hodgkin lymphoma

Non-Hodgkin lymphoma is a cancer originating from lymphocytes, a type of white blood cell which is part of the body's immune system. Non-Hodgkin lymphoma can occur at any age although it is more common in adults over 50 years old. Initial symptoms usually are enlarged lymph nodes, fever, and weight loss. There are many different types of non-Hodgkin lymphoma. These types can be divided into aggressive (fast-growing) and indolent (slow growing) types, and they can be formed from either B lymphocytes (B cells) or in lesser extent from T lymphocytes (T cells) or Natural Killer cells (NK cells). B-cell lymphoma makes up about 85% of non-Hodgkin lymphomas diagnosed in the US. Prognosis and treatment of non-

Hodgkin lymphoma depend on the stage and type of disease.

About Galapagos' T-cell manufacturing platform

Galapagos' decentralized, innovative T-cell manufacturing platform has the potential for the administration of fresh, fit cells within a median vein-to-vein time of seven days, greater physician control 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

We are a biotechnology company with operations in Europe and the U.S. 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, cell therapies, and biologics in oncology and immunology. With capabilities from lab to patient, including a decentralized T-cell 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.glpg.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," as well as similar expressions. Forward-looking statements contained in this release include, but are not limited to, statements regarding new data from the ATALANTA-1 Phase 1/2 study and other analyses related to Galapagos' CD19 CAR-T program, statements related to Galapagos' plans, expectations and strategy with respect to the ATALANTA-1 study, 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 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 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 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.