

## Galapagos to showcase CAR-T point-of-care manufacturing and initial Phase 1/2 CLL data with CD19 CAR-T candidate, GLPG5201, at the EHA 2023 congress

- All 7 out of 7 eligible patients with relapsed/refractory chronic lymphocytic leukemia (rrCLL), with or without Richter’s Transformation (RT), responded to treatment (Objective Response Rate of 100%)<sup>1</sup>
- GLPG5201 showed no cytokine release syndrome (CRS) higher than grade 2, or immune effector cell-associated neurotoxicity syndrome (ICANS)<sup>2</sup>
- A functionally closed, automated manufacturing platform for cell therapies at the point-of-care will be shown at the Galapagos booth A.103 at the EHA 2023 congress

Mechelen, Belgium; 5 June 2023, 22:01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) today announced that it will feature the CAR-T point-of-care manufacturing platform and will present previously disclosed initial Phase 1/2 data with CD19 CAR-T candidate, GLPG5201, at the European Hematology Association (EHA) 2023 congress, taking place from 8 June to 11 June 2023 in Frankfurt, Germany.

“Patients who develop rrCLL and become resistant to new agents have a very poor prognosis and a significant high unmet medical need for novel therapeutic options such as CAR-T cell therapy. The previously disclosed initial efficacy, safety and feasibility data from the ongoing EUPLAGIA-1 study with our CD19 CAR-T candidate, GLPG5201, manufactured at point-of-care, are encouraging, and we are on track to provide Phase 1 topline results around mid this year,” said Jeevan Shetty, Head of Clinical Development Oncology at Galapagos. “Our innovative approach in CAR-T cell therapy development and manufacturing underscores our commitment to accelerating transformational innovation to address the unmet needs of patients with advanced cancers, and we very much look forward to meeting and connecting with you at our booth.”

### Details of the abstract P1399:

Title	Authors	Presentation date/time
Initial Clinical Results of Euplagia-1, a Phase I/II Trial of Point-of-Care Manufactured GLPG5201 in R/R CLL/SLL with or without Richter’s transformation	Nuria Martinez-Cibrian, Sergi Betriu, Valentin Ortiz-Maldonado, Daniel Estban, Leticia Alserawan, Mercedes Montoro, Anna DD van Muyden, Maike Spoon, Margot J. Pont, Christian Jacques, <a href="#">Julio Delgado</a>	<a href="#">Abstract</a> Poster presentation on 9 June 2023, 18:00 - 19:00 CET

At the safety and efficacy analysis cut-off date of 9 January 2023, 7 patients diagnosed with rrCLL (including 4 patients with RT) were enrolled in the EUPLAGIA-1 study (n=4 at dose level 1 (DL1); n=3 at dose level 2 (DL2)). All patients received GLPG5201 as a fresh infusion with a median vein-to-vein time of 7 days. The dose levels that are evaluated in the Phase 1 part of the study are 35x10<sup>6</sup> (DL1), 100x10<sup>6</sup> (DL2) and 300x10<sup>6</sup> (dose level 3 (DL3)) CAR+ viable T cells.

<sup>1</sup> cut-off date for efficacy and safety analysis: 9 January 2023

<sup>2</sup> cut-off date for efficacy and safety analysis: 9 January 2023

The initial results from these 7 patients that were eligible for efficacy analysis (cut-off date: 9 January 2023) indicated that a 7-day vein-to-vein time is feasible and demonstrated strong and consistent *in vivo* CAR-T expansion levels. Moreover, the initial efficacy results are encouraging with an objective response rate (ORR) of 100% observed. 6 out of 7 patients (86%) reached a complete response (CR) and all Richter's patients achieved a CR. A duration of response of up to 7.9 months has been reported and follow-up is ongoing. Only 1 patient (DL1) progressed (progressive disease, (PD) after partial response (PR)) and had a CD19-negative relapse with confirmed RT.

In the safety analysis of these 7 patients, adverse events were consistent with the known toxicities of CD19 CAR-T treatment. None of the patients experienced a CRS higher than grade 2 at both dose levels and no ICANS was reported. No dose limiting toxicities (DLTs) were reported and the majority of grade  $\geq 3$  adverse events were hematological. Only one serious adverse event was reported at DL2 with a patient experiencing a CRS grade 2, but the event was resolved after 7 days. Patient recruitment of the study is ongoing.

### **About point-of-care manufacturing**

CellPoint (a Galapagos company) has developed, in a strategic collaboration with Lonza, a novel point-of-care supply model, which is designed to enable clinicians to administer fresh CAR-T cells within 7 days of leukapheresis, without complex logistics or cryopreservation, thereby aiming to address important limitations of current CAR-T treatments. The proprietary platform consists of CellPoint's end-to-end xCellit workflow management and monitoring software, and Lonza's Cocoon® Platform, a functionally closed, automated manufacturing platform for cell therapies. This novel point-of-care model is compliant with the EMA and FDA guidance for clinical trials.

### **About the EUPLAGIA-1 study (EudraCT 2021-003815-25)**

EUPLAGIA-1 is an ongoing Phase 1/2 open-label, multi-center study evaluating the feasibility, safety, and efficacy of point-of-care manufactured GLPG5201 in patients with rrCLL and small cell lymphocytic lymphoma (rrSLL), with or without RT. GLPG5201 is a second generation anti-CD19/4-1BB CAR-T product candidate, administered as intravenous infusion of a fresh product candidate in a single fixed dose. Patients with CD19+ rrCLL or rrSLL with  $\geq 2$  lines of prior therapy are eligible to participate, and patients with RT are eligible regardless of prior therapy. The primary objective of the Phase 1 part of the study is to evaluate safety and determine the recommended dose for the Phase 2 part of the study. The primary objective of the Phase 2 part of the study is to assess the ORR and the secondary objectives include the analysis of the complete response rate (CRR), duration of response, progression free survival, overall survival, safety pharmacokinetic profile, and feasibility of point-of-care manufacturing.

The dose levels that are evaluated in the Phase 1 part of the study are  $35 \times 10^6$  (DL1),  $100 \times 10^6$  (DL2) and  $300 \times 10^6$  (DL3) CAR+ viable T cells. The study uses a Bayesian Optimal Interval (BOIN) design (n=15 patients) for Phase 1. Following screening and enrolment, patients will receive ibrutinib daily until leukapheresis of mononuclear cells. During GLPG5201 manufacturing, patients receive cyclophosphamide (300 mg/m<sup>2</sup>/day)/fludarabine (30 mg/m<sup>2</sup>/day) for 3 days. After a resting period of at least 2 days, GLPG5201 is administered via intravenous infusion. All patients remain hospitalized for at least 7 days and the end-of-study visit is at Week 14 post CAR-T infusion. Phase 1 patient recruitment is ongoing to establish a recommended dose for Phase 2.

## About chronic lymphocytic leukemia and small cell lymphocytic lymphoma

Chronic lymphocytic leukemia (CLL) is one of the chronic lymphoproliferative disorders (lymphoid neoplasms). It is characterized by a progressive accumulation of functionally incompetent lymphocytes, which are usually monoclonal in origin. CLL and small cell lymphocytic lymphoma (SLL) are essentially the same type of B-cell non-Hodgkin lymphoma (NHL), with the only difference the location where the primary cancer occurs. CLL affects B-cells in the blood and bone marrow and SLL cancer cells are located in lymph nodes and/or the spleen<sup>3</sup>. RT is an uncommon clinicopathological condition observed in patients with CLL. It is characterized by the sudden transformation of the CLL into a significantly more aggressive form of large cell lymphoma and occurs in approximately 2-10% of all CLL patients. CLL/SLL usually follows an indolent course and is an incurable disease. Patients who develop relapsed and refractory disease and become resistant to new agents have a dismal prognosis and a high unmet medical need for new therapeutic options such as CAR-T cells. With estimated incidence of 4.7 new cases per 100,000 individuals, CLL/SLL are the most prevalent lymphoid malignancies and are the most common adult leukemias in the US and in Europe<sup>4</sup>.

## About Galapagos

Galapagos is a fully integrated biotechnology company united around a single purpose: to transform patient outcomes through life-changing science and innovation for more years of life and quality of life. We focus on the key therapeutic areas of immunology and oncology, where we have developed a deep scientific expertise in multiple drug modalities, including small molecules and cell therapies. Our portfolio comprises discovery through to commercialized programs and our first medicine for rheumatoid arthritis and ulcerative colitis is available in Europe and Japan. For additional information, please visit [www.glp.com](http://www.glp.com) or follow us on [LinkedIn](#) or [Twitter](#).

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## Forward-looking statements

*This press release includes forward-looking statements, all of which involve certain risks and uncertainties. These statements are often, but not always, made through the use of words or phrases such as "initial," "feasible," "will," "encouraging," "forward," "aim," "on track," and "planned," as well as any similar expressions. Forward-looking statements contained in this press release include, but are not limited to, statements regarding preliminary, interim and topline data from our studies, including, without limitation, the EUPLAGIA-1 study, and other analyses related to our oncology or CAR-T portfolio, statements regarding our plans and strategy with respect to our oncology or CAR-T portfolio, including, without limitation, the EUPLAGIA-1 study, statements regarding the expected timing, design and readouts of the EUPLAGIA-1 study, including the recruitment for trials and timing for topline results from the EUPLAGIA-1 study, statements regarding the collaboration with Lonza, and statements regarding our R&D and regulatory outlook. Any forward-looking statements in this press release are based on our management's current expectations and beliefs, and*

<sup>3</sup> Wierda WG. Chronic lymphocytic leukemia/ Small lymphocytic lymphoma fact sheet. In: Foundation LR, editor: [https://www.lymphoma.org/wp-content/uploads/2018/04/LRF\\_FACTSHEET\\_CLL\\_SLL.pdf.2018](https://www.lymphoma.org/wp-content/uploads/2018/04/LRF_FACTSHEET_CLL_SLL.pdf.2018)

<sup>4</sup> Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer Statistics, 2021. CA: A Cancer Journal for Clinicians. 2021;71(1):7-33. <https://www.ncbi.nlm.nih.gov/books/NBK493173>

*are not guarantees of future performance. Forward-looking statements may involve unknown and known risks, uncertainties and other factors which might cause our actual results, performance or achievements to be materially different from any historic or future results, performance or achievements expressed or implied by such statements. These risks, uncertainties and other factors include, without limitation, the risk that ongoing and future clinical studies (including the EUPLAGIA-1 study) may not be completed in the currently envisaged timelines or at all, the inherent risks and uncertainties associated with competitive developments, clinical trials, recruitment of patients, product development activities and regulatory approval requirements (including that data from ongoing and planned clinical research programs, including, without limitation, the data from the ongoing EUPLAGIA-1 study, may not support registration or further development due to safety, efficacy, or other reasons, or that data readouts in the future may not reflect interim data results), the inherent risks and uncertainties associated with target discovery and validation or drug discovery and development activities, the risks related to our reliance on collaborations with third parties (including Lonza), and the risk that we will not be able to continue to execute on our currently contemplated business plan and/or will revise our business plan, including the risk that our plans with respect to CAR-T may not be achieved on the currently anticipated timeline or at all. A further list and description of these risks, uncertainties and other factors can be found in our filings and reports with the Securities and Exchange Commission (SEC), including in our most recent annual report on Form 20-F filed with the SEC, as supplemented and/or modified by any other filings and reports that we have made or will make with the SEC in the future. Given these risks and uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. In addition, even if our results, performance or achievements are consistent with such forward-looking statements, they may not be predictive of results, performance or achievements in future periods. These forward-looking statements speak only as of the date of publication of this press release. We expressly disclaim any obligation to update any forward-looking statements in this press release, unless required by law or regulation.*