

Galapagos and CellPoint presented encouraging initial data at ASH 2022 for GLPG5101, a CD19 CAR-T candidate manufactured at point-of-care

- 6 out of 7 eligible patients with relapsed/refractory Non-Hodgkin Lymphoma (rrNHL) responded to treatment (ORR of 86%) and all responding patients achieved complete response (CR)
- No grade 3 or higher cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS) was observed in any of the eligible patients
- Initial data suggest the potential of our decentralized manufacturing and supply model for faster, convenient, and efficient delivery of GLPG5101 at the point-of-care

Mechelen, Belgium; 13 December 2022, 7.00 CET; Galapagos NV (Euronext & NASDAQ: GLPG) and CellPoint (a Galapagos company) today presented encouraging initial data from the ongoing ATALANTA-1 Phase 1/2 study with GLPG5101 at the 64th Annual American Society of Hematology (ASH) Congress taking place in New Orleans, Louisiana, from 10-13 December.

ATALANTA-1 is a Phase 1/2 study in heavily pre-treated rrNHL patients to evaluate the safety, efficacy, and feasibility of GLPG5101, a fresh CD19 CAR-T product candidate manufactured at point-of-care. The dose levels that are evaluated in the Phase 1 part of the study are 50×10^6 (DL1), 110×10^6 (DL2) and 250×10^6 (DL3). As of 8 November 2022, 9 patients were enrolled; baseline and safety data for 8 patients were available (n=4 at DL1; n=4 at DL2). 7 patients reached the follow-up period of 28-days and were eligible for efficacy evaluation.

The initial results from 7 patients that were eligible for efficacy evaluation (cut-off date: 8 November 2022) 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 86% observed and all responding patients achieving a complete response (CR). A duration of response of up to 7 months has been reported and follow-up is ongoing. Two patients who received DL1 that progressed after initial stable disease or CR respectively, had a CD19-negative escape. No CD19-positive relapses have been observed.

In the safety analysis of these 7 patients, adverse events were consistent with the known toxicities of CD19 CAR-T treatment. No grade 3 or higher cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS) was observed in any of the patients. At DL2, CRS grade 1 or 2 was reported in 4 patients and ICANS grade 1 was reported in 3 patients. Patients at DL1 did not experience any grade of CRS or ICANS. Dose-limiting toxicity (neutropenia grade 4 for >21 days) was observed in 1 patient (DL2) and the majority of grade ≥ 3 adverse events were hematological toxicities.

"We are committed to accelerating transformational innovation to address unmet needs of patients with advanced cancers," said Dr. Paul Stoffels¹, CEO and Chairman of the Board of Directors of Galapagos. "Despite significant medical advancements in recent years, many cancer patients relapse, become resistant to treatment or are diagnosed too late. We believe that differentiation and broader access to therapy can come from a disruptive CAR-T manufacturing model at the point-of-care, closer to patients. We are excited to present initial encouraging safety, efficacy and feasibility data from the ATALANTA-1 study with GLPG5101 manufactured at point-of-care, which support that potential. We are on track to report topline data from the completed study in the first half of 2023."

¹ Acting via Stoffels IMC BV

The poster presentation was given by Marie José Kersten, MD, PhD, Professor of Hematology and Head of the Department of Hematology at the Academic Center in Amsterdam:

Abstract Title	Authors	Presentation date/time
Initial Clinical Results of ATALANTA-1, a Phase 1/2 Trial of Point-of-Care Manufactured GLPG5101 (19CP02) in rrNHL	Sébastien Anguille, Ilse Kuipers, Kirsten Saevels, Yves Beguin, Anna Van Muyden, Christian Jacques, and Marie José Kersten	Poster Number: 4637 Date: 12 December 2022, 6:00–8:00 PM ET Session: 704. Cellular Immunotherapies: Early Phase and Investigational Therapies: Poster III

CellPoint 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.

About the ATALANTA-1 study (EudraCT 2021-003272-13)

ATALANTA-1 is an ongoing Phase 1/2, open-label, multicenter study to evaluate the feasibility, safety, and efficacy of point-of-care manufactured GLPG5101, a CD19 CAR-T product candidate, in patients with relapsed/refractory Non-Hodgkin Lymphoma (rrNHL). GLPG5101 is a second generation anti-CD19/4-1BB CAR-T product candidate, administered as an intravenous infusion of a fresh product candidate in a single fixed dose. Each enrolled patient will be followed for 24 months. 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 point-of-care manufacturing of GLPG5101. The planned dose levels that are evaluated in the Phase 1 are 50x10⁶, 110x10⁶ and 250x10⁶ CAR 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 feasibility of point-of-care manufacturing. The study is currently enrolling rrNHL patients in Europe and the first expansion cohort for Mantle Cell Lymphoma, a form of NHL, is currently open for recruitment. The company aims to broaden the study to include US patients in 2023 and to provide topline results in the first half of 2023.

About Non-Hodgkin’s Lymphoma

Non-Hodgkin’s lymphoma is a cancer originating from lymphocytes, a type of white blood cell which is part of the body’s immune system. Non-Hodgkin’s 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’s 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 percent of Non-Hodgkin’s lymphomas diagnosed in the US. Prognosis and treatment of Non-Hodgkin’s lymphomas depend on the stage and type of disease.

About Galapagos

Galapagos is a fully integrated biotechnology company focused on discovering, developing, and commercializing innovative medicines. We are committed to improving patients’ lives worldwide by targeting diseases with high unmet needs. Our R&D capabilities cover multiple drug modalities,

including small molecules and cell therapies. Our portfolio comprises discovery through to Phase 4 programs in immunology, oncology, and other indications. Our first medicine for rheumatoid arthritis and ulcerative colitis is available in Europe and Japan. CellPoint was acquired by Galapagos in June 2022. For additional information, please visit www.glpq.com or follow us on [LinkedIn](#) or [Twitter](#).

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Forward Looking Statements

This press release contains forward-looking statements, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "initial," "feasible" "will," "encouraging," "potential," promising," "believe," "suggest," "on track," and "planned," as well as any similar expressions. Forward-looking statements contained in this release include, but are not limited to, any statements regarding preliminary, interim and topline data from the ATALANTA-1 study and other analyses related to CD19 CAR-T and our plans and strategy with respect to the ATALANTA-1 study and CD19 CAR-T, statements regarding the expected timing, design and readouts of the ATALANTA-1 study, including the expected recruitment for trials and topline results from the ATALANTA-1 study, statements regarding the acquisition of CellPoint, including the anticipated benefits of the acquisition and integration of CellPoint into our portfolio and strategic plans, statements regarding the collaboration with Lonza, statements regarding our regulatory and R&D outlook, and statements regarding our strategy, portfolio goals, business plans, focus, and plans for a sustainable future. Of note, the ATALANTA-1 study is ongoing and these interim results may not continue or be confirmed upon completion of such study. Any forward-looking statements in this release are based on our management's current expectations and beliefs, and 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 may not be completed in the currently envisaged timelines or at all, the inherent risks associated with clinical trial, recruitment of patients for trial, and product development activities, including the CD19 CAR-T clinical program and ATALANTA-1 study, the inherent risks and uncertainties associated with competitive developments, and regulatory approval requirements (including, but not limited to, the risk that data from the ongoing ATALANTA-1 study may not support registration or further development due to safety, efficacy concerns, or other reasons), risks related to the acquisition of CellPoint, including the risk that we may not achieve the anticipated benefits of the acquisition of CellPoint, the inherent risks and uncertainties associated with target discovery and validation or drug discovery and development activities, the risk that the preliminary and topline data from the ATALANTA-1 study may not be reflective of the final data, risks related to our reliance on collaborations with third parties (including CellPoint's collaboration partner Lonza), 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, and risks related to the ongoing COVID-19 pandemic. A further list and description of these or other risks and uncertainties can be found in our filings and reports with the US Securities and Exchange Commission (SEC), including in our most recent annual report on Form 20-F filed with the SEC and our subsequent filings and reports filed with the SEC. 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 release. We expressly disclaim any obligation to update any forward-looking statements in this release, unless required by law or regulation.