High CR and MRD Negativity Rates With GLPG5101, a Fresh, Stem-Like, Early Memory CD19 CAR T With 7-Day Vein-to-Vein Time: Full Results From ATALANTA-1 Cohort 3 (iNHL)

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CONCLUSIONS

The ATALANTA-1 study population included patients with late-stage disease and high-risk disease features, including patients with POD24 (59%) and double refractory disease (72%)

In the ATALANTA-1 fully enrolled Cohort 3 (iNHL), the CR rate was 97%, with an MRD negativity rate of 100% in evaluable patients in CR and durable remission after CAR T-cell infusion

No disease progression has been observed in the 31 responding patients (median follow-up time of 12.3 months); all responses are CRs

The short vein-to-vein time eliminated the need for bridging therapy, and the dropout rate was low (5.9%), which potentially facilitated treatment of patients who would not otherwise be able to receive CAR T-cell therapy

The favorable safety profile of GLPG5101 suggests the potential for future use in an outpatient setting

Introduction

- Patients with relapsed/refractory (R/R) indolent non-Hodgkin lymphoma (iNHL) tend to have shorter remission times with each subsequent line of therapy.[1] Additionally, outcomes for patients with R/R follicular lymphoma (FL) who have high-risk disease features (POD24 or double refractory disease) are suboptimal.[2]
- CD19-targeted CAR T-cell therapies offer the potential for a one-time treatment that can provide durable remission in patients with R/R iNHLs.[2,3]
- Outcomes following CAR T-cell therapy in R/R iNHLs may be improved by short vein-to-vein time,[4–6] and/or by reducing the risk of severe toxicities, which could facilitate outpatient therapy.
- GLPG5101 is a fresh, stem-like, early memory phenotype CD19 CAR T-cell therapy manufactured using a decentralized platform at multiple locations, enabling a 7-day vein-to-vein time.

Methods

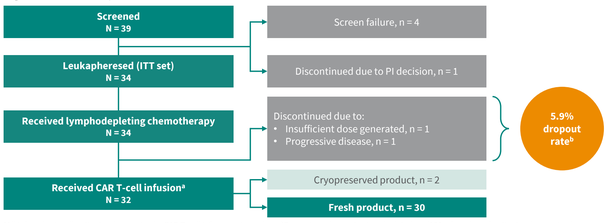
- ATALANTA-1 (CTIS: 2022-502661-23-00; NCT06561425) is an ongoing Phase 1/2 study of GLPG5101 in patients with R/R NHL, including diffuse large B-cell lymphoma, FL, marginal zone lymphoma (MZL), mantle cell lymphoma, Burkitt lymphoma, and primary central nervous system lymphoma.
- The Phase 1 primary objectives are safety and determination of a recommended Phase 2 dose; the Phase 2 primary objective is efficacy (objective response rate).
- Safety, pharmacokinetics, pharmacodynamics, and the feasibility of decentralized manufacturing are assessed as secondary endpoints.

Results

Patient Disposition

- As of 14 October 2024, 32 patients with iNHLs (MZL or FL) received a CAR T-cell infusion (**Figure 1; Table 1**).
- 94% (30/32) of infused patients received a fresh product (**Figure 2**).
- 93% (28/30) of patients who received a fresh product had a vein-to-vein time of 7 days.
- Short vein-to-vein time eliminated the need for bridging therapy.

Figure 1. Patient Disposition



[a]All infused set = all patients who received a CAR T-cell infusion, at any dose. [b]Percentage dropout rate calculated as: (100 − [number of patients who received CAR T-cell infusion / number of patients who were leukapheresed] × 100). Data are pooled across DLs: DL1, 35–50 × 10^6 CAR T cells; DL2, 85–110 × 10^6 CAR T cells. Data cutoff: 14 October 2024. CAR, chimeric antigen receptor; DL, dose level; ITT, intention-to-treat; PI, principal investigator.

Demographics and Baseline Characteristics

- The ATALANTA-1 Cohort 3 included iNHL patients with late-stage disease and high-risk features (**Table 1**).

Table 1. Baseline Demographics and Disease Characteristics

	All patients N = 32
Age, median (range), years	64 (36–81)
Male, n (%)	18 (56)
Female, n (%)	14 (44)
iNHL subtype, n (%)	
FL	27 (84)
MZL	5 (16)
(FL)IPI score at screening, n/n available (%)	
High risk	16/31 (52)
Intermediate risk	11/31 (36)
ECOG PS: 0 / 1 / 2, n (%)	17 (53) / 12 (38) / 3 (9)
mGELF at time of screening, n (%)	26 (81)
Ann Arbor disease stage: II / III–IV, n (%)	6 (19) / 26 (81)
Extra nodal disease, n/n available (%)	14/31 (45)
Bone marrow involvement, n (%)	9 (28)
Bulky disease,[a] n (%)	12 (38)
Tumor burden (SPD), median (range),[b] cm^2	27 (3–112)
Prior systemic therapies, median (range)	3 (2–6)
ASCT, n (%)	10 (31)
Progression of disease within 24 months from start of first-line therapy, n (%)	19 (59)
Relapsed after last line, n (%)	18 (56)
Refractory after last line, n (%)	11 (34)
Double refractory (anti-CD20[+] alkylator), n (%)	23 (72)
Time from diagnosis to CAR T-cell infusion, median (range), years	6.5 (1.5–24.9)
Initial treatment to first PD, median (range), years	2.2 (0.2–8.2)
Time from most recent relapse/refractoriness to CAR T-cell infusion, median (range), years	0.3 (0.1–1.5)

[a]Bulky disease: LDi > 6 cm. [b]Median and range given for 31/32 patients for whom data were available. Data cutoff: 14 October 2024.
ASCT, autologous stem cell transplant; CAR, chimeric antigen receptor; ECOG PS, Eastern Cooperative Oncology Group performance status; FL, follicular lymphoma; (FL)IPI, (FL) international prognostic index; iNHL, indolent non-Hodgkin lymphoma; LDi, longest diameter; mGELF, modified Groupe d'Etude des Lymphomes Folliculaires; MZL, marginal zone lymphoma; PD, progressive disease; SPD, sum of the products of diameters.

Figure 2. Proportion of Patients Receiving Fresh and Cryopreserved Product[a]

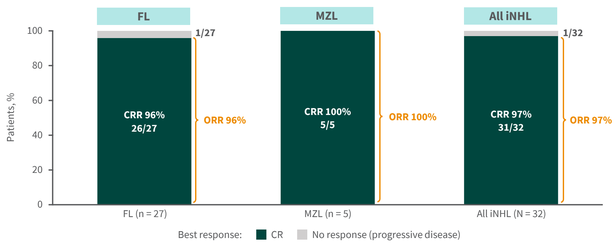


[a]Two patients received cryopreserved product with a vein-to-vein time of 13 days. Data cutoff: 14 October 2024.

Efficacy

- High objective response rates (ORRs) and complete response rates (CRRs) were observed (best response at any time after infusion) (**Figure 3**).
- Per the intention-to-treat population, 31/34 patients responded to treatment (ORR and CRR: 91%).
- All (8/8) patients with available data post-CR were MRD negative and remained in CR at time of data cutoff.
- Durable responses were observed in patients who received a CAR T-cell infusion (**Figure 4**).[b]
- No deaths have been reported, and no relapses have been observed in responding patients, for data available up to 3 March 2025.
- 12-month progression-free survival was high, at 97%, as of 3 March 2025 (**Figure 5**).

Figure 3. Best Response at Any Time After Infusion[a]



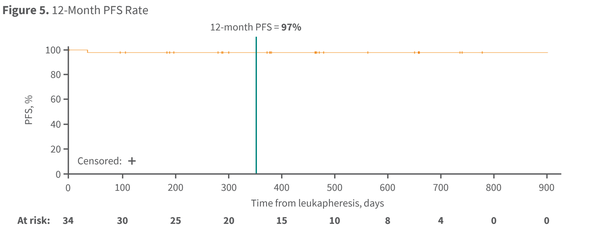
[a]All infused set = all patients who received a CAR T-cell infusion at any dose. Data pooled across DLs (DL1: 35–50 × 10^6 CAR T cells and DL2: 85–110 × 10^6 CAR T cells). Data cutoff: 14 October 2024. CAR, chimeric antigen receptor; CR, complete response; CRR, complete response rate; DL, dose level; FL, follicular lymphoma; iNHL, indolent non-Hodgkin lymphoma; MRD, minimal residual disease; MZL, marginal zone lymphoma; ORR, objective response rate.

Figure 4. Best Response at Any Time After Infusion[a]



[a]Arrows after the last assessment indicate that the patient is still in the study at the time of the data cutoff. Data cutoff: 3 March 2025.
[b]All infused set = all patients who received a CAR T-cell infusion, at any dose. Data are pooled across DLs: DL1, 35–50 × 10^6; DL2, 85–110 × 10^6 CAR T cells.
CAR, chimeric antigen receptor; CR, complete response; D, day; DL, dose level; FL, follicular lymphoma; M, month; MZL, marginal zone lymphoma; PD, progressive disease; PR, partial response; SD, stable disease; W, week.

Figure 5. 12-Month PFS Rate



Data presented for all leukapheresed patients (ITT set), for data available up to 3 March 2025. ITT, intention-to-treat; PFS, progression-free survival.

Safety

- Treatment-emergent adverse events (TEAEs) are summarized in **Table 2**.
- No deaths occurred in the iNHL cohort.
- The most common Grade ≥ 3 TEAEs were hematologic (**Table 2**). All non-hematologic Grade ≥ 3 TEAEs were individual events, reported in 1 patient only.
- No serious or Grade ≥ 3 infections were reported.

Table 2. Treatment-Emergent Adverse Events

	All patients N = 32
Any TEAE, n (%)	30 (94)
GLPG5101-related TEAE, n (%)	27 (84)
Serious TEAE, n (%)	6 (19)
TEAE leading to death, n (%)	0
Grade ≥ 3 TEAE, n (%)	24 (75)
Hematologic Grade ≥ 3 TEAEs, n (%)	
Neutropenia[a]	22 (69)
Leukopenia[b]	13 (41)
Lymphopenia[c]	10 (31)
Thrombocytopenia[d]	5 (16)
Anemia[e]	4 (13)
Prolonged cytopenia,[f] Grade ≥ 3, n/n available (%)	
30 days after infusion	11/32 (34)
60 days after infusion	8/29 (28)
90 days after infusion	9/28 (32)
180 days after infusion	4/26 (15)

[a]Includes neutropenia/neutrophil count decreased. [b]Includes leukopenia/white blood cell count decreased. [c]Includes lymphopenia/lymphocyte count decreased. [d]Includes thrombocytopenia/platelet count decreased. [e]Includes anemia/hemoglobin decreased. [f]Includes all events related to neutropenia, thrombocytopenia, anemia, and lymphopenia. Data cutoff: 14 October 2024. TEAE, treatment-emergent adverse event.

CRS and ICANS

- No Grade ≥ 3 CRS and one Grade 3 ICANS were reported (**Table 3**).
- Median (range) time to CRS onset was 7.0 (1–13) days and duration of CRS was 3.0 (1–9) days.*
- Median (range) time to ICANS onset was 5 (2–12) days and duration of ICANS was 1.5 (1–2) days.*
- The most common treatments used for CRS/ICANS toxicity were dexamethasone and tocilizumab in 13% and 19% of patients with CRS and 9% and 6% of patients with ICANS, respectively.

Table 3. CRS and ICANS, All Grades

	All patients N = 32
CRS, n (%)	11 (34)
Grade 1	5 (16)
Grade 2	6 (19)
Grade 3	0
ICANS, n (%)	4 (13)
Grade 1	3 (9)
Grade 2	0
Grade 3	1 (3)

Data cutoff: 14 October 2024. CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome.

Product Characterization and Pharmacokinetics*

- CAR T-cell expansion was robust and demonstrated durable persistence.
- In Phase 1 and Phase 2 patients:
  - 13/13 (100%) of evaluable patients had persisting CAR T cells at Month 9 post-infusion.
  - Persisting CAR T cells were detected up to 21 months post-infusion.
- The proportion of early phenotype $CD4^+$ and $CD8^+$ CAR T cells increased significantly in the final product, compared with the early phenotype $CD4^+$ and $CD8^+$ T cells in the starting material.

Disclosures: J.S.P.V. has nothing to declare. **S.A.** has nothing to declare. **M.T.K.** reports consultancy/advisory role for Adicet Bio, Biotec, BMS, Galapagos, Janssen, Kite/Gilead, Miltenyi, Mustang Bio, and Novartis; honoraria from Beigene, BMS, Kite/Gilead, and Roche; and travel grants from AbbVie, BMS, and Roche. **P.G.N.J.M.** has nothing to declare. **E.W.** reports travel support from Beigene and Takeda. **M.R.B.** reports consultancy/advisory role for Autolus Therapeutics, AvenCell Therapeutics, BMS/Juno Therapeutics, Chimeric Therapeutics, CRISPR Therapeutics, Galapagos, Kite/Gilead, inBbio, Incyte, Iovance Biotherapeutics, Novartis, and Sana Biotechnology; honoraria from AbbVie, ADC Therapeutics, AstraZeneca, Autolus Therapeutics, AvenCell Therapeutics, BMS, BMS/Juno Therapeutics, Chimeric Therapeutics, CRISPR Therapeutics, Galapagos, GenmAb, inBbio, Incyte, Iovance Biotherapeutics, Kite/Gilead, Novartis, Sana Biotechnology, and Servier; and speaker fees from AbbVie, ADC Therapeutics, AstraZeneca, BMS, GenmAb, Incyte, Kite/Gilead, and Servier. **T.J.A.D.** has nothing to declare. **M.D.** reports consultancy/advisory role for AbbVie, AstraZeneca, Beigene, BMS/Celgene, Janssen, Kite/Gilead, Lilly/Loxo, Novartis, and Roche; honoraria from AstraZeneca, Beigene, Janssen, Kite/Gilead, Lilly, Novartis, and Roche; and research support (institution) from AbbVie, Bayer, BMS/Celgene, Janssen, Kite/Gilead, Lilly, and Roche. **C.J.** reports consultancy/advisory role for AbbVie, ADC Therapeutics, Aleta, Appia, AstraZeneca, BMS, Caribou, Galapagos, Genentech, GenmAb, Janssen, Kite/Gilead, Kyverna, Miltenyi, Novartis, Sana Biotechnology, and Synthekine. **C.L-B., E.H., S.M., E.S., M.S., A.V.M., C.V.** are employees of Galapagos. **K.V.H.** is an employee of Open Analytics and Galapagos. **M.J.K.** reports consultancy/advisory role for Adicet Bio, Biotec, BMS, Galapagos, Janssen, Kite/Gilead, Miltenyi, Mustang Bio, and Novartis; honoraria from Beigene, BMS, Kite/Gilead, and Roche; and travel grants from AbbVie, BMS, and Roche.

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*For further details of B-cell aplasia, CRS and ICANS events, product characterization, and cellular kinetics, see the supplementary information accessed via the QR code.

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