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Outpatient treatment with glofitamab plus gemcitabine and oxaliplatin (Glofit-GemOx) in relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL): Preliminary safety results from a Phase 2 study

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Summary

In the Phase 3 STARGLO trial, Glofit-GemOx showed significant improvements in survival benefits versus rituximab-GemOx in patients with R/R DLBCL

We report preliminary safety results from an ongoing Phase 2 trial evaluating cytokine release syndrome (CRS) profile optimization to enhance convenience for administration of Glofit-GemOx without hospitalization

Data support a convenient strategy for outpatient administration of Glofit-GemOx in R/R DLBCL without mandatory hospitalization for CRS monitoring

Data show administration of Glofit-GemOx with steroid premedication enhanced patient convenience in R/R DLBCL, with hospitalization not required for most CRS events occurring after the first glofitamab dose

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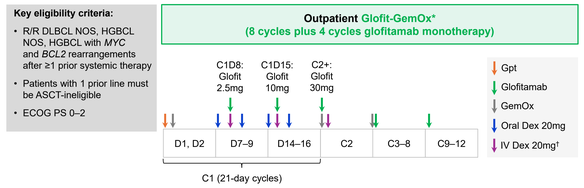
Background

- Glofitamab, a CD20xCD3 bispecific antibody, in combination with GemOx showed significant improvements versus rituximab-GemOx in overall survival and progression-free survival in the randomized Phase 3 STARGLO trial in autologous stem-cell transplant (ASCT)-ineligible patients with R/R DLBCL.[1,2]
- The observed CRS profile with Glofit-GemOx in STARGLO allows for treatment without mandatory hospitalization.
- Implementing strategies for administration without hospitalization can further improve patient convenience and optimize healthcare resource utilization.
- We present preliminary safety results from an ongoing Phase 2 trial (GO45434; NCT06806033), evaluating CRS profile optimization for administration of Glofit-GemOx without hospitalization via enhanced steroid premedication and a revised monitoring regimen in R/R DLBCL.

Phase 2, open-label, multicenter trial

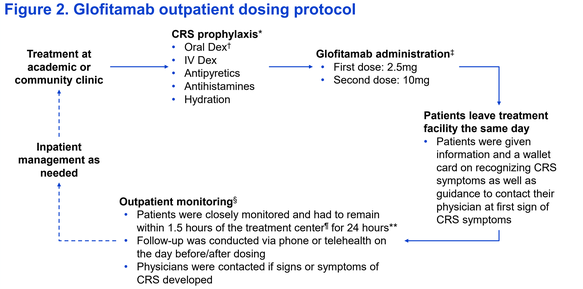
- Patients had R/R DLBCL; those with 1 prior line of therapy had to be ASCT-ineligible (**Figure 1**).
- Patients received oral dexamethasone (Dex) 20mg one day prior to and after glofitamab step-up dosing (SUD) in Cycle (C) 1, in addition to the premedication used in the STARGLO trial.
- Patients were monitored in the outpatient setting for 4 hours after infusion during SUD and 90 minutes after the first target dose, in both academic and community centers (**Figure 2**).
- The primary endpoint was CRS incidence. Secondary endpoints included other safety parameters and efficacy.
- All patients provided written informed consent.

Figure 1. Study design



*Glofit-GemOx was administered as per label.[3] †IV Dex was optional in C3–12 for patients who tolerated ≥1 glofitamab 30mg dose without experiencing CRS.
D, Day; ECOG PS, Eastern Cooperative Oncology Group performance status; Gpt, obinutuzumab pretreatment; HGBCL, high-grade B-cell lymphoma; IV, intravenous; NOS, not otherwise specified.

Figure 2. Glofitamab outpatient dosing protocol



*Tocilizumab prophylaxis was not used. †One day prior and day after infusion of the first two glofitamab infusions. ‡4 hours of infusion and 4 hours of CRS monitoring. §Patients who experienced Grade ≥2 CRS monitored their temperature regularly on the day of administration and the day after. ¶Or another facility with access to emergency medical care in close proximity to the treatment center. **Clinic follow-up visit on C1D9.

Baseline characteristics

- At data cut-off (March 23, 2026), 56 patients with R/R DLBCL had received ≥1 dose of study treatment.
- Overall, 71.4% of patients had 1 prior line of therapy, 28.6% had ≥2 prior lines of therapy, 62.5% were refractory to any therapy, and 57.1% were refractory to their last line of therapy (**Table 1**).

- Most glofitamab doses were administered without hospitalization: 88.9% of glofitamab 2.5mg doses on C1D8, 88.7% of glofitamab 10mg doses on C1D15, and 93.6% of all glofitamab 30mg doses in C2
  - At data cut-off, a total of 93.9% of glofitamab doses across all cycles (C1–12) were administered in the outpatient setting
  - Twenty-two glofitamab doses were not administered in the outpatient setting; reasons for dosing or monitoring not occurring in the outpatient setting across all cycles were: pre-planned hospitalization (13 doses; 3.6%), patient's clinical condition (6 doses; 1.7%), and other reasons (3 doses; 0.8%)
  - Overall, 79.6% (43/54) of glofitamab-exposed patients received all doses of glofitamab in the outpatient setting.

Table 1. Demographic and baseline characteristics

% (n), unless stated	N=56
Median age, years (range)	73.5 (32.0–88.0)
Male	30 (53.6)
ECOG PS	
0	26 (46.4)
1	25 (44.6)
2	5 (8.9)
Ann Arbor stage	
I–II	10 (17.9)
III–IV	46 (82.1)
Bulky disease (≥10cm)	7 (12.5)
Number of prior lines of therapy	
Median (range)	1.0 (1.0–4.0)
1	40 (71.4)
≥2	16 (28.6)
Prior CAR T-cell therapy	9 (16.1)
Prior ASCT	1 (1.8)
Refractory to any prior therapy	35 (62.5)
Refractory to last prior therapy	32 (57.1)

CAR, chimeric antigen receptor.

CRS events were all low grade and manageable

- CRS events were reported in 35.7% of patients (**Table 2**)
  - Three patients had more than one CRS episode
  - No CRS led to treatment discontinuation.
- CRS events mainly occurred during C1 (**Figure 3**).
- Three patients who had a dose delay of ≥6 weeks between treatment received repeated SUD in C5, and no CRS events occurred.
- Four patients had their first CRS event in later cycles (C2, n=1; C3, n=1; C4, n=2).
- CRS events resolved within a median of 2 days (**Table 3**).

Table 2. CRS* summary by highest grade

n (%)	N=56
Any grade	20 (35.7)
Grade 1	14 (25.0)
Grade 2	6 (10.7)
Grade ≥3	0
Any serious CRS event†	7 (12.5)

*CRS was graded using the ASTCT criteria.[4] †Defined as an AE that results in death, is life-threatening, requires or prolongs hospitalization, results in persistent disability, or is deemed medically significant.
AE, adverse event; ASTCT, American Society for Transplantation and Cellular Therapy.

Figure 3. CRS events by cycle and grade

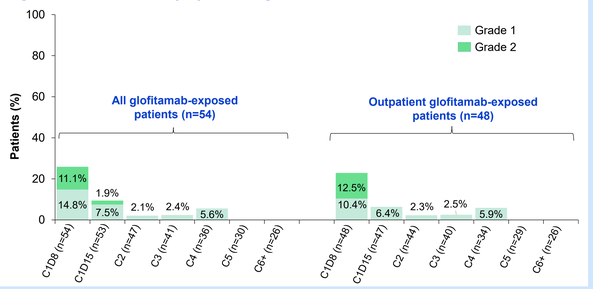


Table 3. CRS onset and duration by cycle in patients who experienced CRS

	C1D8 (N=54)	C1D15 (n=53)	C2 (n=47)	C3 (n=41)	C4 (n=36)
Patients who experienced CRS, days (range)	14	5	1	1	2
Median time from last glofitamab dose, hours (range)	10.5 (2.6–29.2)	17.3 (13.6–31.1)	NR*	15.4 (15.4–15.4)	NR*
Median duration, days (range)	2 (1–4)	1 (1–1)	2 (2–2)	1 (1–1)	1 (1–1)

*Median time from last glofitamab dose for C2 and C4 has not been reported due to potential data entry errors reported by sites. NR, not reported.

- Among patients who developed CRS in C1D8, 7/14 (50.0%) patients received tocilizumab and 3/14 patients received steroids
  - One patient who had Grade 2 CRS in C1D8 was treated with low flow oxygen
  - Six patients required hospitalization in C1D8.
- In C1D15, CRS was managed with tocilizumab and fluids (2/5 patients each)
  - Hospitalization was required for 2/5 patients.
- One patient (each) received tocilizumab after C2 and C3 (both events were Grade 1).

The safety profile of Glofit-GemOx in the outpatient setting was manageable, with low rates of AEs leading to treatment discontinuation

- Median number of glofitamab treatment cycles was 5.0 (range: 1.0–12.0).
- Immune effector cell-associated neurotoxicity syndrome (ICANS) events were reported in 7.1% of patients; no Grade ≥4 events occurred (**Table 4**)
  - All events resolved within 2 days, and none led to treatment discontinuation.
- Two patients had ICANS concurrent with CRS (after the 2.5mg glofitamab dose).
- Infections occurred in 32.1% of patients and were mostly Grade 1–2 (17.9%)
  - Grade 3–4 infections occurred in 12.5% of patients and one patient had a Grade 5 infection (COVID-19 pneumonia)
  - No infections led to treatment discontinuation.

Table 4. Safety summary by highest grade

n (%)	N=56
Any grade AE	53 (94.6)
Grade 1	3 (5.4)
Grade 2	16 (28.6)
Grade 3	20 (35.7)
Grade 4	11 (19.6)
Grade 5	3 (5.4)*
Serious AEs	23 (41.1)
AEs leading to treatment discontinuation	7 (12.5)
Anemia,† any grade	19 (33.9)
Grade 3–4	10 (17.9)
Neutropenia,‡ any grade	15 (26.8)
Grade 3–4	11 (19.6)
Thrombocytopenia,§ any grade	27 (48.2)
Grade 3–4	15 (26.8)
ICANS¶	4 (7.1)**
Grade≥3 febrile neutropenia	3 (5.4)

*COVID-19 pneumonia (patient was not exposed to glofitamab), pulseless electrical activity and general physical health deterioration, n=1 each. †Group term anemia and hemoglobin count decreased. ‡Group term neutropenia and neutrophil count decreased. §Group term thrombocytopenia and platelet count decreased. ¶By ASTCT. **Grade 1, n=2; Grade 2 and Grade 3, n=1 each.

Conclusions

- The majority of patients with R/R DLBCL had Glofit-GemOx administered and monitored successfully in the outpatient setting, with hospital admission only when needed.
- Most patients (89%) received the first glofitamab dose in an outpatient clinic, and the majority of subsequent CRS events were managed without requiring hospital admission.
- Overall, the CRS and broader safety profile are comparable with the established Glofit-GemOx safety profile reported in the STARGLO trial.
- These data support a more convenient strategy for outpatient administration and monitoring of Glofit-GemOx in R/R DLBCL.

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