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Glofitamab plus gemcitabine and oxaliplatin (GemOx) versus rituximab plus GemOx (R-GemOx) in patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL): Outcomes from the 3-year follow-up of STARGLO

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Summary

In the Phase 3 STARGLO trial, glofitamab combined with GemOx (Glofit-GemOx) demonstrated a statistically significant and clinically meaningful survival benefit versus R-GemOx in patients with R/R DLBCL

At 3 years of follow-up, Glofit-GemOx continued to demonstrate a substantial clinical benefit versus R-GemOx, with more pronounced efficacy observed in the second-line (2L) setting

This updated analysis supports Glofit-GemOx as a potentially curative, off-the-shelf treatment for autologous stem cell transplant (ASCT)-ineligible patients with R/R DLBCL

Glofit-GemOx was well tolerated, with no new safety signals identified

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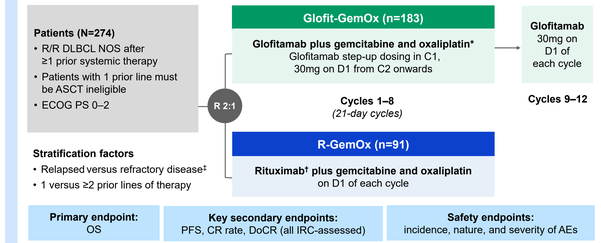
Background

- Glofitamab is a CD20xCD3 bispecific antibody approved as a fixed-duration monotherapy in patients with R/R DLBCL after ≥2 prior lines of therapy (LOT).[1,2]
- In the global Phase 3 STARGLO trial (NCT04408638), Glofit-GemOx demonstrated significant improvements in overall survival (OS), progression-free survival (PFS), and complete response (CR) rate when compared with R-GemOx in ASCT-ineligible patients with R/R DLBCL after ≥1 prior LOT[3]
  - Glofit-GemOx is approved in this setting in >50 countries, including in the EU.[2]
- We report updated efficacy and safety data for Glofit-GemOx versus R-GemOx from the STARGLO trial, with 3 years of follow-up.

Phase 3 STARGLO trial (Figure 1)

Figure 1. Study design



*Gemcitabine 1000mg/m^2 and oxaliplatin 100mg/m^2. In C1, obinutuzumab pretreatment was administered on D1, GemOx on D2, glofitamab 2.5mg on D8, glofitamab 10mg on D15; in C2–8, glofitamab 30mg and GemOx administered on D1. †Rituximab 375mg/m^2. ‡Relapsed disease: recurrence after a response that lasted ≥6 months after completion of last line of therapy; refractory disease: disease that did not respond to, or that progressed <6 months after completion of last line of therapy. AEs, adverse events; C, cycle; D, day; DoCR, duration of complete response; ECOG PS, Eastern Cooperative Oncology Group performance status; IRC, independent review committee; NOS, not otherwise specified; R 2:1, randomized in a 2:1 ratio.

Baseline characteristics were balanced across treatment arms

- At data cut-off (May 1, 2025), of the 274 patients enrolled, 172 (62.8%) had 1 prior LOT (2L setting) and 102 (37.2%) had ≥2 prior LOT (third line or later setting) (**Table 1**).
- A retrospective central analysis of 118/274 (43.1%) patients with available tissue for fluorescence in situ hybridization revealed that 4/41 (9.8%) R-GemOx-treated and 7/77 (9.1%) Glofit-GemOx-treated patients had double-hit DLBCL (*MYC* and *BCL2*).

Table 1. Baseline characteristics (intent-to-treat population)

n (%) unless otherwise stated	Overall		2L	
	R-GemOx (n=91)	Glofit-GemOx (n=183)	R-GemOx (n=57)	Glofit-GemOx (n=115)
Age, years				
Median (range)	69.0 (20–84)	68.0 (22–88)	70.0 (28–84)	71.0 (24–88)
≥65 years	57 (62.6)	116 (63.4)	44 (77.2)	86 (74.8)
Sex, male	53 (58.2)	105 (57.4)	32 (56.1)	61 (53.0)
Race				
Asian	51 (56.0)	86 (47.0)	30 (52.6)	48 (41.7)
White	34 (37.4)	82 (44.8)	24 (42.1)	53 (46.1)
Black or African American	1 (1.1)	2 (1.1)	0	2 (1.7)
Unknown/not reported	5 (5.5)	13 (7.1)	3 (5.3)	12 (10.4)
ECOG PS	(n=88)	(n=180)	(n=55)	(n=112)
0 or 1	81 (92.0)	160 (88.9)	49 (89.1)	98 (87.5)
2	7 (8.0)	20 (11.1)	6 (10.9)	14 (12.5)
Ann Arbor stage	(n=90)			
I or II	20 (22.2)	60 (32.8)	12 (21.1)	39 (33.9)
III or IV	70 (77.8)	123 (67.2)	45 (78.9)	76 (66.1)
Number of prior LOT				
1	57 (62.6)	115 (62.8)	57 (100)	115 (100)
≥2	34 (37.4)	68 (37.2)	0	0
Primary refractory	47 (51.6)	106 (57.9)	28 (49.1)	67 (58.3)
Refractory to last LOT	54 (59.3)	112 (61.2)	29 (50.9)	60 (52.2)
Bulky disease, ≥10cm	(n=90)			
Present	14 (15.6)	23 (12.6)	11 (19.3)	15 (13.0)
Prior CAR T-cell therapy	8 (8.8)	15 (8.2)	0	0

The intent-to-treat population included all randomized patients. CAR, chimeric antigen receptor.

Efficacy: Glofit-GemOx continued to demonstrate favorable outcomes versus R-GemOx at 3 years of follow-up

- Median OS follow-up was 35.1 months (95% confidence interval [CI]: 33.6–37.6).
- Outcomes were superior with Glofit-GemOx versus R-GemOx (**Table 2**)
  - Median OS: 25.5 versus 12.5 months (hazard ratio [HR], 0.60; 95% CI: 0.43–0.8)
  - Median PFS: 14.4 versus 3.3 months (HR, 0.41; 95% CI: 0.29–0.57).

Efficacy (cont'd)

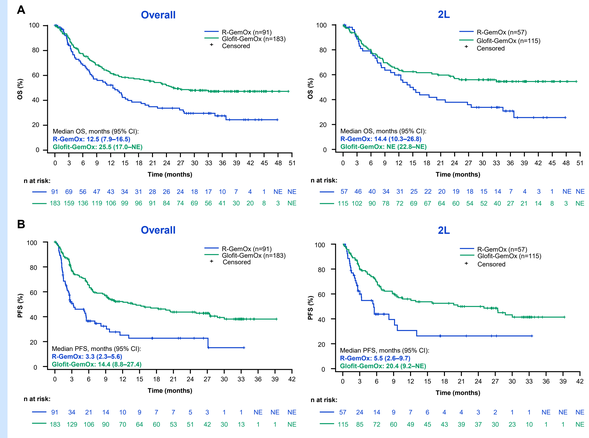
- A more pronounced efficacy benefit was observed for Glofit-GemOx versus R-GemOx in the 2L setting (**Table 2**; **Figure 2**)
  - Median OS: not estimable (NE) versus 14.4 months (HR, 0.58; 95% CI: 0.38–0.89)
  - Median PFS: 20.4 versus 5.5 months (HR, 0.49; 95% CI: 0.31–0.78).

Table 2. Efficacy summary (intent-to-treat population)

	Overall		2L	
	R-GemOx (n=91)	Glofit-GemOx (n=183)	R-GemOx (n=57)	Glofit-GemOx (n=115)
36-month OS, % (95% CI)	27.4 (17.3–37.5)	47.1 (39.5–54.6)	30.8 (17.7–44.0)	54.6 (45.2–64.0)
30-month PFS, % (95% CI)	15.2 (0.9–29.5)	38.1 (29.8–46.3)	26.3 (10.3–42.4)	41.5 (30.8–52.2)
ORR, n (%)	37 (40.7)	125 (68.3)	28 (49.1)	83 (72.2)
CR, n (%)	23 (25.3)	107 (58.5)	16 (28.1)	73 (63.5)
Median DoCR, months (95% CI)	24.2 (6.9–NE)	NE (27.2–NE)	NE (6.5–NE)	NE (24.8–NE)

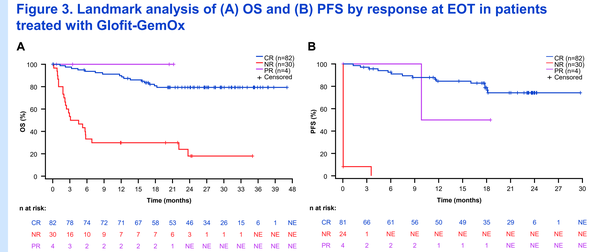
ORR, overall response rate.

Figure 2. Analysis of (A) OS and (B) PFS in the overall population and in the 2L setting



- In Glofit-GemOx-treated patients with a CR at end of treatment (EOT), median OS and PFS were not reached (**Figure 3**)
  - OS rate 24 months after EOT: 79.4% (95% CI: 70.3–88.4)
  - PFS rate 24 months after EOT: 74.2% (95% CI: 62.6–85.8).

Figure 3. Landmark analysis of (A) OS and (B) PFS by response at EOT in patients treated with Glofit-GemOx



NR, no response; PR, partial response.

The safety profile was unchanged with extended follow-up

- No new AEs were reported since the last data cut. No new safety signals were identified, and there was no evidence of cumulative toxicity or new long-term AEs (**Table 3**).
- In glofitamab-exposed patients, cytokine release syndrome (CRS) remained the most common AE, and was mostly Grade 1–2.
- Events consistent with immune effector cell-associated neurotoxicity syndrome occurred in four patients (all concurrent with CRS; most Grade 1–2 [n=3]).

Safety (cont'd)

- COVID-19 was the most common infection in both treatment arms, occurring during the COVID-19 pandemic.

Table 3. Safety summary (safety population)

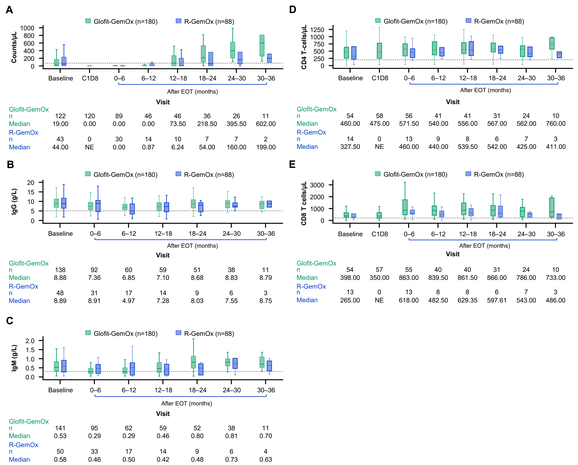
n (%) unless otherwise stated	R-GemOx (n=88)	Glofit-GemOx (Glofit-exposed) (n=172)
Any Grade AE	85 (96.6)	172 (100)
Grade 3–4 AE	36 (40.9)	119 (69.2)
Grade 5 (fatal) AE	4 (4.5)	13 (7.6)
Serious AE	15 (17.0)	90 (52.3)
AE leading to discontinuation*	3 (3.4)	13 (7.6)
CRS†	0	77 (44.8)
Grade 1	0	55 (32.0)
Grade 2	0	18 (10.5)
Grade 3	0	4 (2.3)
Grade 3–5 infections‡	11 (12.5)	34 (19.8)

The safety population comprised all patients who received at least one dose study treatment. *Treatment-related AEs leading to discontinuation of glofitamab or rituximab. †No CRS events were Grade 4–5. ‡COVID-19 infection (any Grade, Grade 3–4, and Grade 5, respectively) occurred in 8 (9.1%), 2 (2.3%), and 0 patients in the R-GemOx arm and 28 (16.3%), 4 (2.3%), and 3 (1.7%) in the Glofit-GemOx arm.

Immuno-recovery was observed and Glofit-GemOx did not reduce T-cell count

- Median B-cell and immunoglobulin (Ig) counts were above the lower limit of normal 18–24 months after EOT; B-cell depletion on treatment was rapid (**Figure 4A–C**).
- CD4 and CD8 T-cell levels were stable during and after treatment (**Figure 4D–E**).

Figure 4. Analysis of (A) B-cell, (B) IgG, (C) IgM, (D) CD4 T-cell, and (E) CD8 T-cell levels during and after treatment



Box plots show median and range; whiskers show 95% CI; dotted lines represent the lower limit of normal (B cells, 70cells/µL; IgG, 5g/L; IgM, 0.3g/L; CD4 T cells, 200cells/µL; CD8 T cells, 200cells/µL.

Conclusions

- After 3 years of follow-up, clinical benefits with Glofit-GemOx were sustained, demonstrating superior OS, PFS, and CR rates versus R-GemOx
  - A pronounced efficacy benefit was observed for Glofit-GemOx versus R-GemOx in patients treated in the 2L setting
  - The majority of Glofit-GemOx-treated patients with a CR at EOT remained alive and progression free 2 years after EOT.
- The safety profile remained consistent with the known risks of each study drug and was manageable. No new AEs were reported.
- B cell and Ig recovery were observed within 18–24 months after EOT. Glofit-GemOx treatment did not reduce T-cell count.
- Glofit-GemOx demonstrates sustained survival benefits and durable remissions, positioning it as a potentially curative, off-the-shelf therapy for patients with ASCT-ineligible R/R DLBCL.

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