

Outcomes of real-world complete responders after fixed-duration glofitamab in relapsed/refractory large B-cell lymphoma

CD20×CD3 bispecific antibodies (BsAb) induce complete remissions (CR) in a substantial number of patients with relapsed/refractory large B-cell lymphoma (r/r LBCL)^{1,2} yet outcomes of real-world complete responders remain insufficiently characterized. We retrospectively analyzed 52 consecutive patients with r/r LBCL who achieved CR after glofitamab monotherapy at 25 centers across Germany, Austria, Switzerland and Italy between August 2021 and February 2025 (data cut-off: February 1, 2026). All patients received glofitamab as standard of care or compassionate use outside interventional clinical trials and provided consent as per local regulations. The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Review Board of the University of Muenster (2024-317-f-S). Most patients maintained durable remissions with favorable survival and limited late relapse. A CONSORT diagram summarizing patients’ selection is provided in *Online Supplementary Figure*

S1. Overall, 232 patients with r/r LBCL received glofitamab monotherapy during the study period, corresponding to a CR rate of 22.4% (52/232). The cohort of collected patients had received a median of three prior lines of therapy, with 63.5% having received a prior chimeric antigen receptor T-cell (CAR-T) therapy. Radiographic/metabolic CR were confirmed by investigators based on Lugano response criteria, including the Deauville assessment. The most common LBCL entities were *de novo* diffuse large B-cell lymphoma (DLBCL) (35/52), transformed indolent lymphoma (11/52) and high-grade B-cell lymphoma (6/52) (Table 1). The median age at BsAb initiation was 67 years. Thirty-eight percent of patients received BsAb in third-line treatment and 62% in later lines. At treatment initiation 51.6% had a high-intermediate or high International Prognostic Index. Because this cohort includes only CR patients, baseline features describe the responding population and

Table 1. Characteristics of the study cohort.

Parameters	Values	Parameters	Values
Demographics		Cellular therapies prior to glofitamab, N (%)	
Patients, N (%)	52 (100)	CAR-T	33 (63.5)
Age at lymphoma diagnosis, years, median (IQR)	62 (54-72)	Early CAR-T failure (0-3 months)	8 (24.2)
Age at glofitamab administration, years, median (IQR)	67 (57-76)	Intermediate CAR-T failure (4-6 months)	9 (27.3)
Male, N (%)	22 (42.3)	Late CAR-T failure (>6 months)	16 (48.5)
Lymphoma types, N (%)		Autologous HSCT	14 (26.9)
DLBCL <i>de novo</i>	35 (67.3)	Allogeneic HSCT	4 (7.7)
GCB (Hans <i>et al.</i>)	10 (19.2)	Disease features prior to glofitamab	
Non-GCB (Hans <i>et al.</i>)	13 (25.0)	Bulky (>7.5 cm), N (%)	7 (13.5)
Unclassifiable	12 (23.1)	Extranodal lesions, N (%)	31 (59.6)
DLBCL transformed from any indolent lymphoma	11 (21.2)	LDH prior to glofitamab, U/L, median (IQR)	289 (239-372)
HGBL with <i>MYC</i> & <i>BCL2</i> rearrangements	5 (9.6)	LDH > upper limit of normal, prior to glofitamab, N (%)	40 (76.9)
HGBL, not otherwise specified	1 (1.9)	Secondary IPI at glofitamab initiation, N=48, N (%)	
Timing of BsAb treatment		IPI low (0-1)	8 (16.7)
Time from diagnosis to glofitamab, months, median (IQR)	26 (17-55)	IPI low-intermediate (2)	15 (31.1)
BsAb in third-line, N (%)	20 (38.5)	IPI high-intermediate (3)	12 (24.5)
BsAb in fourth-line or beyond, N (%)	32 (61.5)	IPI high (4-5)	13 (27.1)
Therapies prior to glofitamab		Refractory to last treatment, N (%)	18 (34.6)
N of lines, median (range)	3 (2-6)	Types of BsAb administered	
Anti-CD20/anthracycline-based, N (%)	45 (86.5)	Glofitamab, N (%)	52 (100)
Platinum-based salvage, N (%)	34 (65.4)		
Bendamustine/rituximab +/- polatuz. , N (%)	13 (25)		
Bendamustine within last 6 months prior to glofitamab, N (%)	3 (5.8)		
Tafasitamab/lenalidomide, N (%)	13 (25)		
PD-1 inhibitor, N (%)	3 (5.8)		
Ibrutinib, N (%)	1 (1.9)		

Percentages refer to total number of events scored. IQR: interquartile range; DLBCL: diffuse large B-cell lymphoma; GCB: germinal center B-cell like-type; HGBL: high-grade B-cell lymphoma; BsAb: bispecific antibody; polatuz: polatuzumab vedotin; PD-1: programmed cell death protein 1; HSCT: hematopoietic stem cell transplantation; CAR-T: chimeric antigen receptor T cells; LDH: lactate dehydrogenase; IPI: International Prognostic Index.

are not intended to imply prognostic enrichment.

Baseline clinical parameters among complete responders were moderate. Almost 77% presented with elevated lactate dehydrogenase (40/52), 34.6% were refractory to their last therapy preceding glofitamab, and, among those previously exposed to CAR-T, 48.5% had had a late relapse (>6 months). CR was documented by positron emission tomography-computed tomography (PET-CT) in 63.5% of cases and in 36.5% by radiological imaging (CT) (Table 1, *Online Supplementary Table S1*).

At the time of last follow-up, no patients were receiving ongoing glofitamab therapy. Thirty-six patients (69.2%) had completed 12 cycles without any subsequent consolidation, five (9.6%) had discontinued due to toxicity, and one (1.9%) had discontinued because of a secondary malignancy. Three (5.8%) underwent CAR-T consolidation and four (7.7%) underwent allogeneic stem cell transplantation as consolidation after a maximum of five cycles of glofitamab. One more patient (1.9%) underwent allogeneic stem cell transplantation after completing 12 cycles of glofitamab. Two patients (3.8%) discontinued treatment due to progression (*Online Supplementary Table S1*).

The median time to documented CR was 136 days (range, 17-360). At a median follow-up of 21.2 months after BsAb initiation, eight patients (15.4%) experienced relapse or

progression and 13 (25%) died, including four due to r/r disease and nine from non-relapse causes (infection, N=5; bleeding, N=1; secondary malignancy, N=1; unknown, N=2, all in CR). Of those relapsing, two relapsed during ongoing BsAb therapy and six relapsed after the end of treatment (5 after 12 cycles, 1 after 7 cycles of glofitamab discontinued because of coronavirus disease 2019 [COVID-19] infection). Four patients died from r/r disease at data cut-off. Notably, four of five fatal infections occurred in patients in sustained CR after the regular end of treatment with 12 cycles of glofitamab, with 1, 6, 8, and 10 months elapsing between the end of treatment and death. This corresponds to a relapse-related mortality of 7.7% and a non-relapse mortality rate of 17.3%.

Overall, 24 out of 52 patients experienced any infection (46%) with a grade ≥ 3 infection documented in 13 patients (25%). Infectious complications were mostly due to bacterial (N=15; 29.8%) and viral (N=16; 30.8%) agents, with COVID-19-related events observed in 12 patients (23.1%). One other patient also had a fungal infection in addition to bacterial and viral infections. Acyclovir (400 mg twice daily) and cotrimoxazole (960 mg twice daily 2 days/week or 960 mg once daily 3 days/week) were used as prophylaxis. Immunoglobulin replacement therapy could be employed in cases in which patients exhibited serum IgG levels below

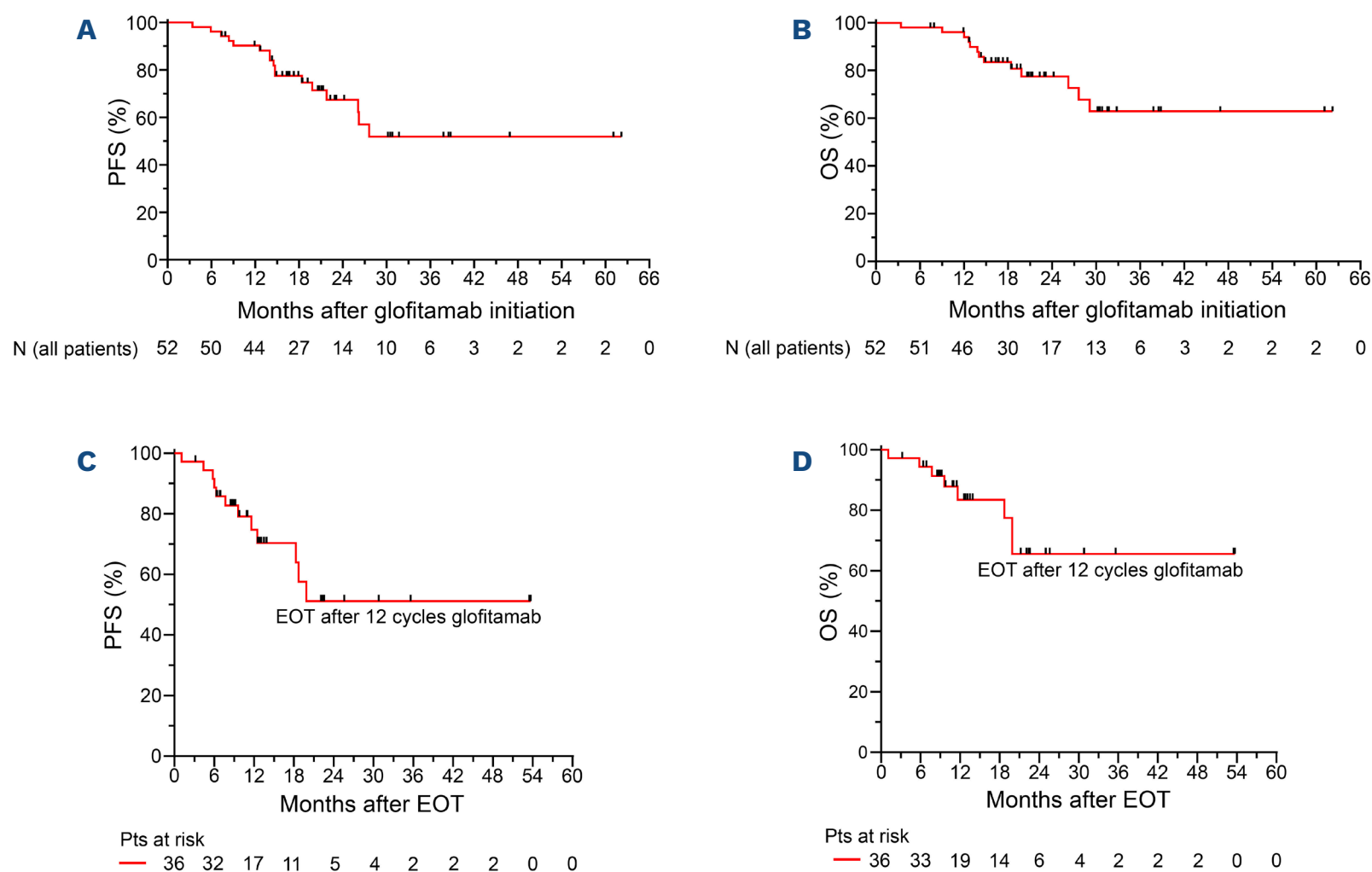


Figure 1. Survival outcomes of the patients with relapsed/refractory large B-cell lymphoma in complete remission following a treatment with glofitamab. (A) Progression-free survival for all patients. (B) Overall survival for all patients. (C) Progression-free survival for patients after the end of treatment. (D) Overall survival for patients after the end of treatment. The *P* values were obtained using a log-rank test and patients at risk are highlighted below the Kaplan-Meier plots. PFS: progression-free survival; OS: overall survival; EOT: end of treatment; Pts: patients.

4 g/L and experienced recurrent or severe infections; 21 of 52 patients (40.4%) received immunoglobulin replacement therapy. Kaplan-Meier estimates showed a 1-year progression-free survival (PFS) of 90% and 1-year overall survival (OS) of 94% after BsAb initiation in patients achieving CR (Figure 1A, B). Among patients who completed all 12 cycles of glofitamab (N=36; 69.2%), the 1-year PFS and OS after the end of treatment were 69.0% and 83.0%, respectively (Figure 1C, D). Patients with early treatment termination

for non-relapse causes (N=7; 13.4%) showed a 1-year PFS of 71.0% and OS of 71.0% after the end of treatment. Those who underwent consolidation with either CAR-T therapy or allogeneic hematopoietic stem cell transplantation (N=7; 13.4%) demonstrated a 1-year PFS and OS of 86% after consolidation. Accordingly, the median duration of CR was not reached. The individual patients' trajectories are shown in the swimmer plot (Figure 2). Overall, CR remains a key prerequisite for achieving durable

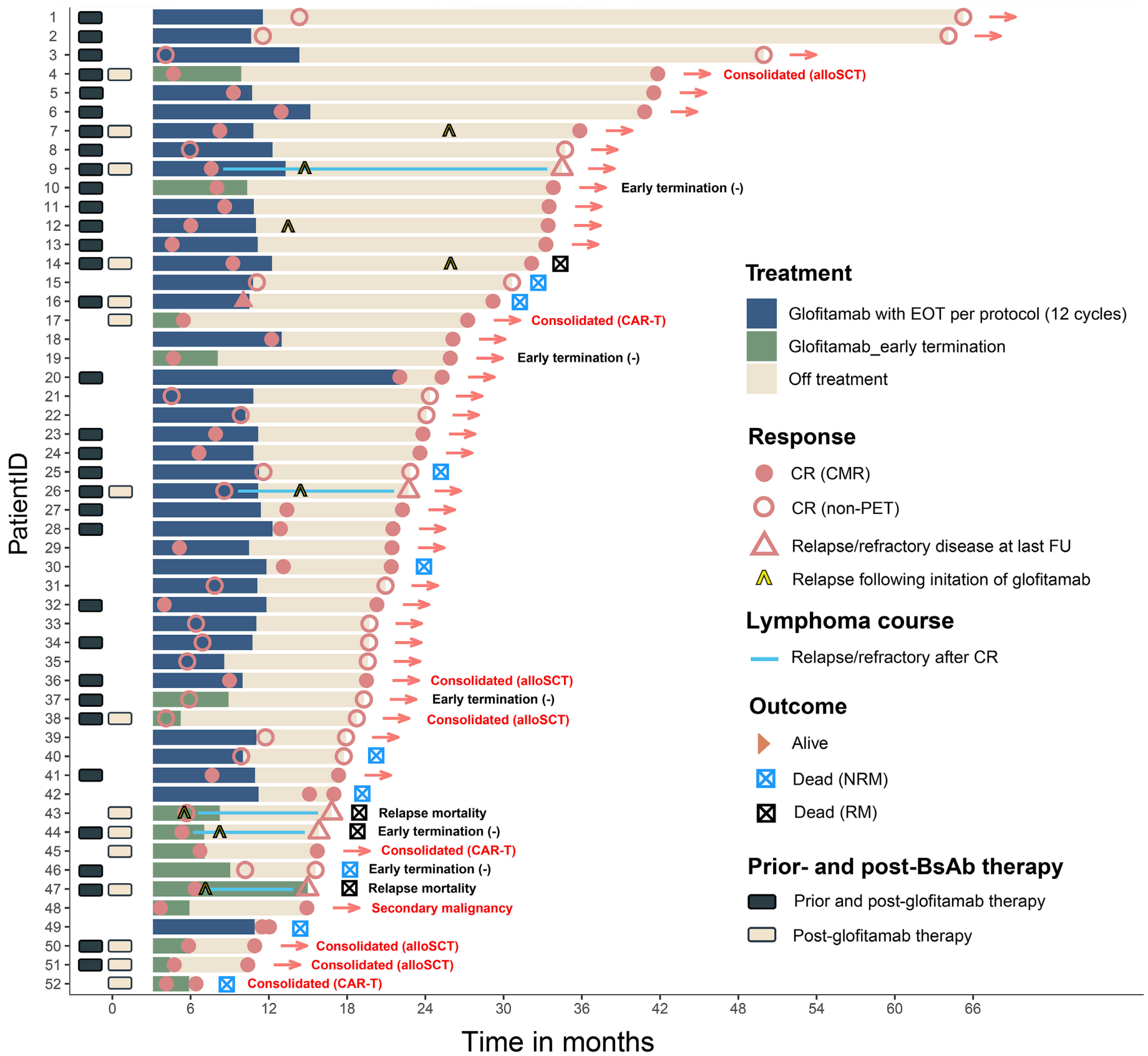


Figure 2. Swimmer plot visualizing the timing and durability of responses and highlighting treatment in all patients of this cohort. alloSCT: allogeneic stem cell transplantation; CAR-T: chimeric antigen receptor T-cell therapy; EOT: end of treatment; CR: complete remission; CMR: complete metabolic remission; PET: positron emission tomography; FU: follow-up; NRM: non-relapse mortality; RM: relapse-related mortality; BsAb: bispecific antibody.

disease control in r/r LBCL. The introduction of BsAb has revolutionized treatment and prognosis in heavily pretreated patients. As BsAb development followed the clinical introduction of CAR-T therapies, their curative potential in the real-world setting is still being defined. In the last follow-up of the glofitamab pivotal study, the median CR duration was 29.8 months, with 2-year PFS and OS rates of 57% and 77%, respectively, in patients with CR at the end of treatment.³ Although the follow-up in our analysis is shorter, and patients were more heavily pretreated (2/3 vs. 1/3 after CAR-T treatment), our data are so far in line with the above-mentioned studies, with most patients maintaining durable remissions with favorable survival and limited late relapses, supporting the potential for sustained, treatment-free disease control after fixed-duration BsAb therapy. However, given the retrospective design and limited follow-up of this analysis, so far cure cannot be reliably inferred, and longer observation will be required to define long-term outcomes.

In our previous real-world analyses, CR rates with BsAb reached up to 27.1% in patients who had received a median of four prior therapy lines.^{4,5} A further real-world analysis by Brooks *et al.* showed a CR rate of 30%.⁶ In the present analysis, the CR rate was 22.4%. So far, combinations of BsAb with chemotherapy or biologicals have shown – albeit in indirect comparisons – greater efficacy than BsAb monotherapy. Despite the short follow-up, CR and survival rates of such combinations in patients who had failed at least one previous treatment line are promising and approach responses of patients treated with CAR-T (*Online Supplementary Table S2*).^{1–3,7–14} In the STARGLO trial, glofitamab plus gemcitabine/oxaliplatin achieved a 58.5% metabolic CR rate and a median OS of 25.5 months in transplant-ineligible patients after at least one prior line of therapy.⁸ In patients with a CR at the end of treatment (N=82), the 1-year PFS and OS rates were 82.4% and 89.3%, respectively.¹⁵ The EPCORE NHL-2 study evaluated epcoritamab in combination with gemcitabine/oxaliplatin in transplant-ineligible patients after at least two prior lines of therapy, reporting a CR rate of 61% and a median OS of 21.6 months.¹⁶ At present, whether BsAb combinations should bridge to or even replace CAR-T therapies remains an open question, and no direct comparison between BsAb-based combinations and CAR-T efficacy can be made based on this analysis. Notably, patients with early BsAb termination due to toxicity or who were consolidated also demonstrated excellent outcomes in our cohort.

Beyond efficacy, our analyses highlight the still inadequately recognized risk of infection-related mortality in patients treated with BsAb. Our data are in line with the infection rates reported in the pivotal trials,^{1,2} indicating the need for close follow-up even in patients with ongoing CR. Immune profiling, including IgG levels, but possibly also biomarkers of the patients' cellular immune status such as CD4⁺ T-cell subsets, T-cell receptor repertoire diversity, or delayed

CD19⁺ recovery, may identify patients early who are at risk of developing serious infections. Subsequent measures can include immunoglobulin replacement, antibiotic and antiviral prophylaxis, as well as vaccination strategies to mitigate the risk of preventable infections.

In summary, BsAb monotherapy with glofitamab can induce durable CR in heavily pretreated r/r LBCL patients. The limitations of our study are a relatively short median follow-up, the retrospective design, investigator-assessed response evaluation, the lack of standardized imaging schedules across centers and a relatively small cohort size. However, this reflects the infrequent occurrence of CR in the real-world setting and the exploratory nature of this analysis is acknowledged.

Non-relapse mortality, rather than relapse mortality, was the leading cause of death among our patients in CR after BsAb. To this end, infection-related non-relapse mortality, especially after the end of treatment, poses a critical challenge. As BsAb will move into earlier lines of treatment of patients with aggressive B-cell lymphomas, long-term risk mitigation with improved anti-infectious prophylactic and therapeutic strategies should become a key element of clinical development to unlock the full therapeutic potential of these agents.

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Contributions

EShu, RW-K and GL conceived the project and wrote the paper. ES, RW-K, JK, MW, PM, UN, HB, NG, UH, AH, MTa, PMN, CK, PB, TM, VZ, CW, PN, CS-F, GFV, VL, IK, FK, UV-K, AO-S, HH, AB, MB, JKS, PG, US, VV, ESho, SG, AK, SS, SA, KM, UB, KW, BG, TO, FA, FH, LT, ML, MH, CWS, MTo, CP, PD, DM, SD, ED, BC, BvT, TP, FM and GL provided patients' data. ES, RW-K, MW, PM, and GL analyzed the data. All authors approved the final manuscript.

Data-sharing statement

De-identified individual participants' data are available from the corresponding author upon reasonable request, subject to institutional approvals and applicable data-protection regulations.

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