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Prolonged survival with glofitamab in non-diffuse large B-cell lymphoma after CAR T-cell therapy relapse

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Data Availability Statement

All data provided are anonymized to respect the privacy of participants in the trial, in line with applicable laws and regulations. Data requests pertaining to the manuscript may be made to the corresponding author (G.C.; g-cartron@chu-montpellier.fr). Requests will be processed within 12 weeks. The remaining data are available within the article and Supplementary Information. For original data, please contact the LYSA/LYSARC data protection officer at dpo@lysarc.org, who will respond to your

request in compliance with the applicable data protection regulations, data security requirements and principles of data minimization, subject to the contractual provisions.

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Author Contributions

G.C., P.S., Y.A.L., K.T. and C.L. contributed to the conception, design, and planning of the study. G.C., R.H., Y.A.L., F.L.B., L.Y., S.C., F.J., J-O.B, F-X.G., F.M., C.Ro., T.G., C.T., M.J., L.R., C.R., L.D.L.R., P.F., A.M., S.G., K.T., C.L., and P.S. contributed to the acquisition and analysis of data. G.C., R.H., Y.A.L., F.L.B., L.Y., S.C., F.J., J-O.B, F-X.G., F.M., C.R., T.G., C.T., M.J., L.R., C.Ro., L.D.L.R., P.F., A.M., S.G., K.T., C.L., and P.S. contributed to the critical review and revision of the manuscript. All authors approved the final version of the manuscript and are accountable for all aspects of the work.

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Letter to the Editor

CAR T-cell therapy has emerged as a cornerstone in the management of relapsed or refractory (R/R) B-cell non-Hodgkin lymphomas (B-NHL), with approvals in R/R follicular lymphoma (FL), mantle cell lymphoma (MCL), and large B-cell lymphomas (LBCL). Relapse or progression after anti-CD19 chimeric antigen receptor (CAR) T-cell therapy remains a major therapeutic challenge in B-NHL (1), and median overall survival after CAR T-cell therapy failure remains extremely poor (5-7 months), highlighting the critical need for more effective post-CAR treatment strategies (2–5). Bispecific antibodies that redirect CD3-positive T-cells to CD20-expressing B-cells, such as glofitamab, have emerged as potent options capable of inducing durable responses in heavily pretreated, aggressive LBCL patients, including those undergoing CAR T-cell therapy (6–9). We previously reported results from the BiCAR study, conducted by the Lymphoma Study Association (LYSA), showing that glofitamab provides meaningful clinical activity and durable remissions in patients with diffuse large B-cell lymphoma (DLBCL) NOS or high-grade B-cell lymphoma (HGBCL) relapsing after CAR T-cell therapy. (10) and outperformed non-bispecific treatments in a matched comparison from the DESCAR-T registry (11). However, data on glofitamab after CAR T-cell exposure in non-LBCL remain limited. Available evidence is largely derived from small subgroup analyses, such as those including transformed FL (t-FL) or primary mediastinal B-cell lymphoma (PMBL), or from earlier studies conducted before the widespread use of CAR T-cell therapy. As a result, the activity of glofitamab in non-DLBCL/HGBCL patients previously exposed to CAR T-cells is still poorly characterized (5,6,8,12). Here,

we report the final analysis of the BiCAR study in patients with non-DLBCL/HGBCL, including PMBL, MCL, FL and other indolent non-Hodgkin lymphomas (iNHL) with histologic transformation, who received glofitamab after relapse or progression following CAR T-cell therapy.

The BiCAR study (Clinical-Trials.gov registration submitted on January 4, 2021: NCT04703686), a LYSA single-arm multicenter phase 2 trial, enrolled participants with R/R B-NHL in 19 centers in France. The study protocol was approved by the French Ethics Committee Ile de France (Aulnay Sous-Bois; no. 20.12.08.60717, ID 10596), in accordance with applicable French laws and regulations. The study included two cohorts based on B-NHL subtype. In this report, we present the final results of the primary and secondary endpoints for cohort 2, enrolling participants aged ≥ 18 years with non-DLBCL/HGBCL who experienced relapse or progression immediately after CAR T-cell infusion. Treatment consisted of obinutuzumab premedication on day-3, followed by a short ramp-up schedule of glofitamab: 2.5 mg on day 1, 10 mg on day 3, and 30 mg on day 8, followed by 11 cycles every three weeks (10). Overall survival (OS) was measured from the date of the first glofitamab infusion to the date of death from any cause, censoring participants who were still alive at the analysis cutoff date. Key secondary endpoints included objective response (OR) and complete response (CR) rates after cycles 2, 6, 9 and at the end of treatment, defined as end of cycle 11 or at permanent treatment discontinuation of glofitamab, whichever occurred first. Metabolic responses were reviewed by PET/CT according to Lugano 2014 criteria (13)

and assessed by both the investigator and a central independent review panel. Other secondary efficacy endpoints included progression-free survival (PFS), duration of response (DoR) and duration of CR (DoCR). The PFS was measured from the first glofitamab infusion to the first observation of documented disease progression according to independent review or death because of any cause. DoR was defined from the time of first CR or PR to the date of first documented disease progression, relapse, or death from any cause. Secondary safety endpoints included the incidence, nature, and severity of adverse events. Adverse effects of special interest included cytokine release syndrome (CRS) and neurotoxicity (ICANS) (14). Other adverse events were graded using CTCAE v5.0.

Between May 2021 and April 2023, 20 participants were screened, and 19 patients from 19 LYSA centers received at least one dose of glofitamab, constituting the full analysis set (FAS). Cohort 2 included six patients with a FL (31.6%), five with a MCL (26%), four with t-FL (21.1%), two with transformed marginal zone lymphoma (t-MZL) (10.5%), one patient with PMBL (5.3%), and one with transformed Waldenström macroglobulinemia (t-WM, 5.3%). Participant demographics and disease characteristics of the FAS (n = 19) are summarized in Table 1. The median age at glofitamab initiation was 66 years (range, 42–76), and 63% were male. All participants (100%) had ECOG performance status 0-1, and 84.2% had an Ann Arbor stage III or IV. The median number of prior treatment lines was 3 (range, 3-6), including CAR T-cell therapy. At baseline, 18 participants (94.7%) had relapsed or progressed after the CAR T-cell therapy, including

16 patients (84.2%) within 6 months after CAR T-cell infusion. One participant (5.3%) did not achieve a metabolic response (*i.e* no metabolic response or stable disease).

At a median follow-up of 37.2 months (95% CI, 32.1–37.7, range: 0.4–37.9), the median OS was 29.2 months (95% CI: 6.2–NA; range: 0.2 –37.8) (Figure 1A), with a 2-year OS rate of 52.6% (95% CI, 28.7-71.9). The best OR rate was 57.9%, and the CR rate was 52.6% according to central review. Complete responses were observed in most of all histologic subtypes: FL: 3/6 (50%), MCL: 3/5 (60%), PMBL: 0/1, t-FL: 3/4 (75%), t-MZL: 1/2 (50%), t-WM: 0/1. The median PFS was 3.9 months (95% CI: 1.1– NA; range: 0.2 – 37. 8), and the median DoR was not reached (95% CI: 2.2– NA; range: 1.4–36.7) (Figure 1B et 1C and supplemental Figure). The median duration of complete response (DoCR) was not reached (95% CI: 1.4– NA; range: 1.4–36.7).

All the patients (100%) received at least one full dose (30 mg) of glofitamab (median: 6 cycles, range 2-11). No reduction dose of glofitamab was observed in this cohort. Grade ≥ 3 adverse events occurred in 14 patients, most commonly neutropenia (47.4%), thrombocytopenia (26.3%), and respiratory infections (21.1%), including COVID-19 pneumonia (10.5%). CRS occurred in 3 patients (15.8%), all grade 1-2. One patient experienced grade 2 ICANS. No grade ≥ 3 CRS or neurotoxicity events occurred. Infectious complications occurred in 10 patients (52.6%), with grade ≥ 3 infections reported in 8 patients (42.1%). Febrile neutropenia was observed in one participant (5.3%). The most frequent infections included respiratory tract infection, COVID-19, sepsis and viral infection. A detailed breakdown of infectious events by type and grade

is provided in Table 2. No treatment-related deaths were observed; all deaths were attributable to lymphoma progression (70%) or concurrent illness (30%).

These results indicate that glofitamab may provide durable clinical benefit in selected patients with certain non-DLBCL/HGBCL subtypes relapsing after CAR T-cell therapy, addressing a critical unmet medical need. The median OS was 29.2 months. While this figure compares favorably with historical data for patients progressing after CAR T-cell therapy, positioning glofitamab as a practice-changing therapeutic option in this high-risk population. (2-6) However, these results should be interpreted with caution given the limited sample size and potential selection bias inherent in a small cohort. A notable observation in this updated analysis is the plateauing of the survival curves between months 6 and 24. This suggests that patients who achieve a CR and remain progression-free during the first 6 months of treatment are likely to experience prolonged remissions. This stability of response is particularly encouraging in this heavily pretreated population where late relapses after subsequent lines of therapy are typically common. Notably, this is the first prospective, multicenter trial specifically designed to evaluate a bispecific antibody in non-DLBCL/HGBCL after CAR T-cell therapy, providing level of evidence to guide clinical decision-making in a setting previously lacking dedicated prospective data.

Complete responses were observed in the majority of histologic subtypes represented in this cohort, although the small number of patients with PMBL and t-WM did not achieve a CR. These clinical observations may indicate that CD20 target accessibility and T-cell functionality remain sufficiently preserved despite prior CAR T-cell exposure

and associated lymphodepletion. This trans-histologic efficacy has immediate clinical implications, as CAR T-cell therapy indications continue to expand beyond DLBCL/HGBCL to include FL and MCL, creating a growing population of patients who will require effective salvage options. The manageable safety profile, with no grade ≥ 3 CRS or neurotoxicity, confirms the tolerability of the short step-up schedule and distinguishes glofitamab from the more complex toxicity profile associated with CAR T-cell therapies.

These findings build upon our recently published results in 46 DLBCL NOS /HGBCL patients from cohort 1 of the BiCAR trial, which demonstrated not only the efficacy of glofitamab but also its superiority compared to non-bispecific therapies in a matched comparison from the DESCAR-T registry (10,11). By extending these observations to non-LBCL subtypes, the current study provides comprehensive evidence suggesting the clinical activity of glofitamab across several aggressive B-cell lymphoma subtypes following CAR T-cell failure. However, further data are needed for rarer entities not represented in our cohort. This consistency of benefit strengthens the therapeutic rationale for integrating bispecific antibodies into post-CAR T-cell treatment algorithms as a class effect that may extend beyond glofitamab to other CD20-directed bispecific antibodies.

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Table 1. Patient characteristics at inclusion

Characteristics	N=19
Male, N (%)	12 (63.2)
Median age, yrs (range)	66 (42-76)
ECOG 0-1, (%)	19 (100)
Ann Arbor Stage III/IV, (%)	16 (84.2)
NHL subtypes	
FL	6 (31.6)
MCL	5 (26.3)
t-FL	4 (21.1)
t-MZL	2 (10.5)
PMBL	1 (5.3)
t-WM	1 (5.3)
CD20 expression, (%)	
Positive	14 (93.3)
Negative	1 (6.7)
Missing data	4
Median number of previous lines of therapy, (range)	3 (3-6)
CAR T-cells infused as previous line	

Axi-Cel	5 (26.3)
Tisa-Cel	8 (42.4)
Brexu-Cel	5 (26.3)
Exp.product	1 (5.3)
Refractory to CAR T-cells (NMR, PD), (%)	1 (5.3)
Relapse/progression after CAR T-cells, (%)	18 (94.7)
1-3 mo	6 (33.3)
3-6 mo	10 (55.6)
> 6 mo	2 (11.1)

Abbreviations: ECOG: Eastern Cooperative Oncology Group; Exp.: experimental product; FL : follicular lymphoma; MCL : mantle cell lymphoma; Mo: months; NHL : non-hodgkin lymphoma; NMR : non-metabolic response; PD : progressive disease; PMBL : primary mediastinal B-cell lymphoma; t-FL : transformed follicular lymphoma; t-MZL : transformed marginal zone lymphoma; t-MW: transformed Waldenstrom macroglobulinemia ; yrs : years

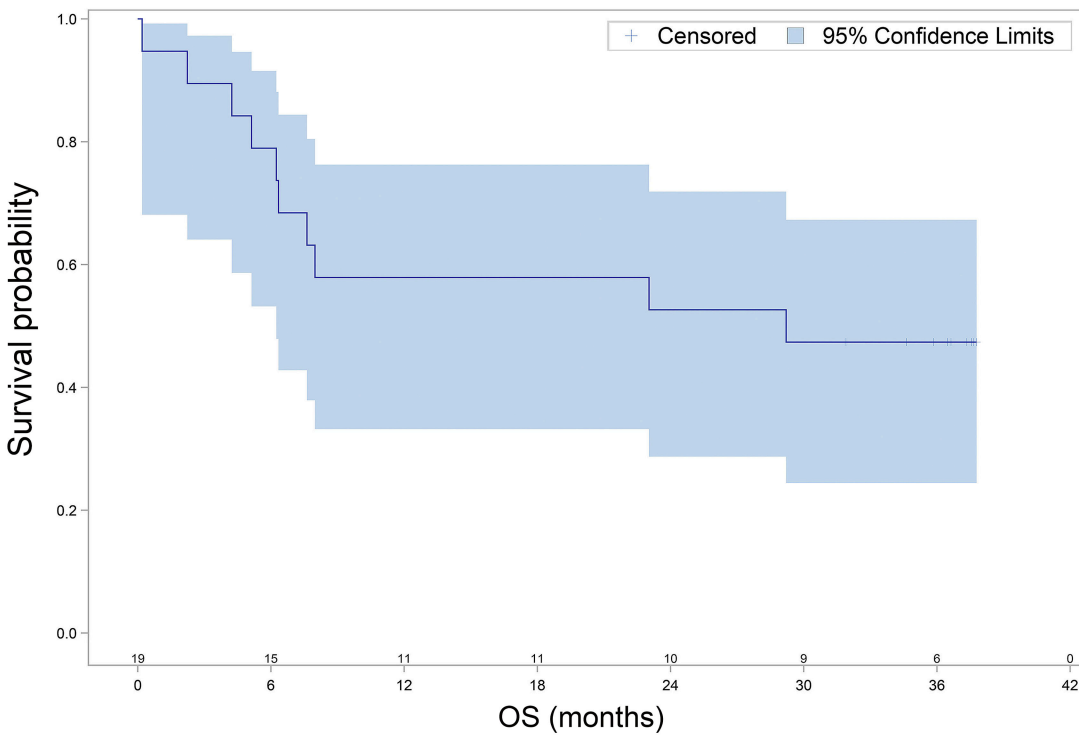
Table 2. Infection type and grade

Type of infection	Grade
Viral infection, (N)	
Grade 3	2
Respiratory tract infection, (N)	
Grade 2	4
Grade 3	2
Sepsis, (N)	
Grade 4	1
Grade 5*	1
Covid-19 pneumoniae, (N)	
Grade 2	1
Grade 3	2
Covid-19, (N)	
Grade 3	1
Urinary tract infection, (N)	
Grade 2	1

* Grade 5 sepsis events were assessed as unrelated to obinutuzumab or glofitamab treatment.

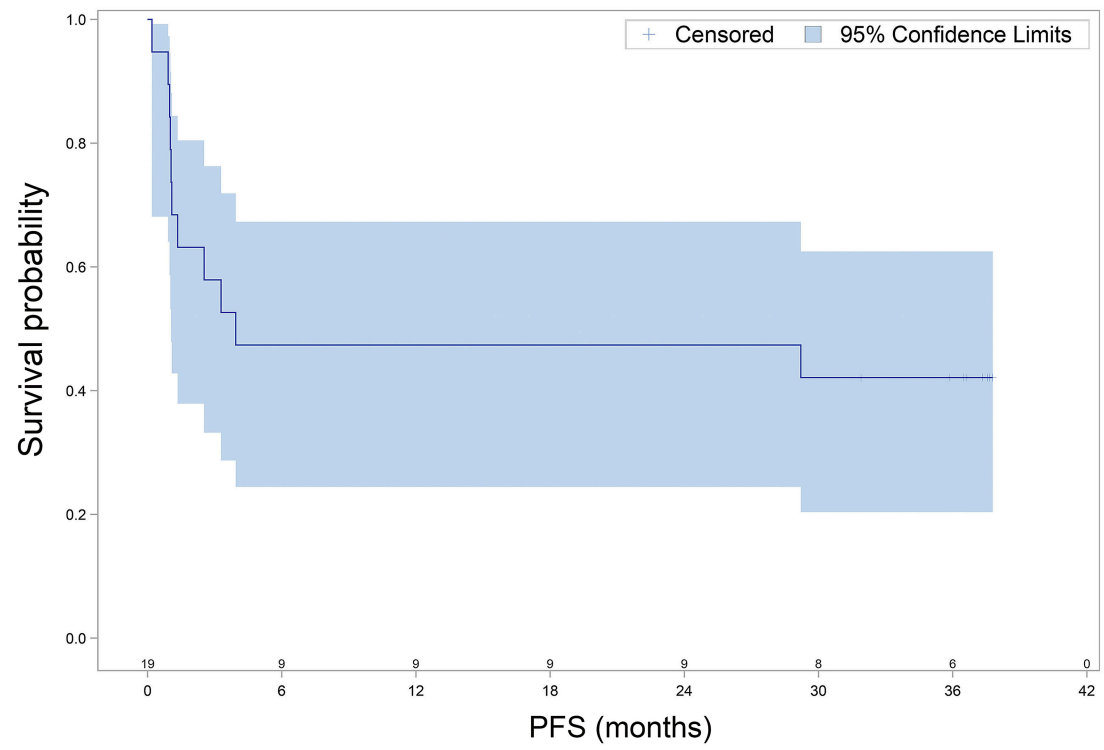
Figure 1. Patient outcomes of patients receiving glofitamab as the treatment of first relapse/progression after CAR T-cell therapy. Kaplan–Meier curve for overall survival (A), progression-free survival (B) and duration of response (C).

Overall Survival – Cohort 2 - FAS
With number of subjects at risk



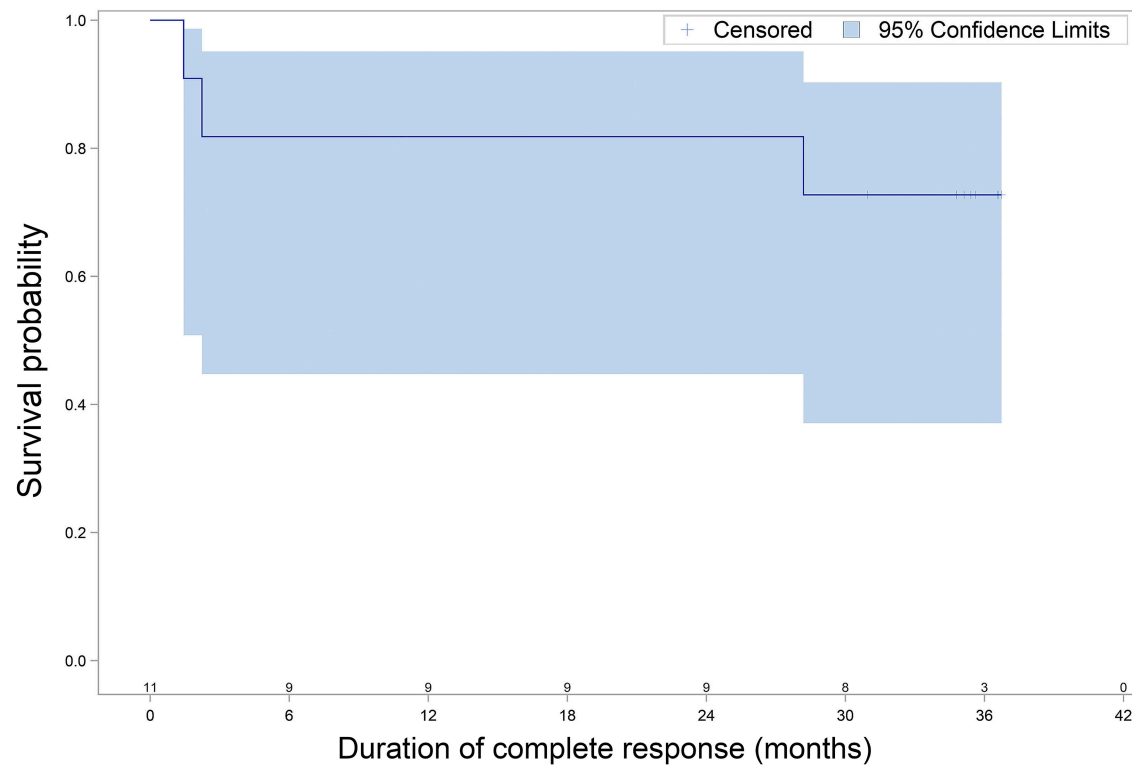
No. of subjects	Event	Censored	Median survival (95% CI)
19	52.6 % (10)	47.4 % (9)	29.2 (6.2 ; NA)

PFS since C1D1 of Glocitab - Cohort 2 - FAS
With number of subjects at risk



No. of subjects	Event	Censored	Median survival (95% CI)
19	57.9 % (11)	42.1 % (8)	3.9 (1.1 ; NA)

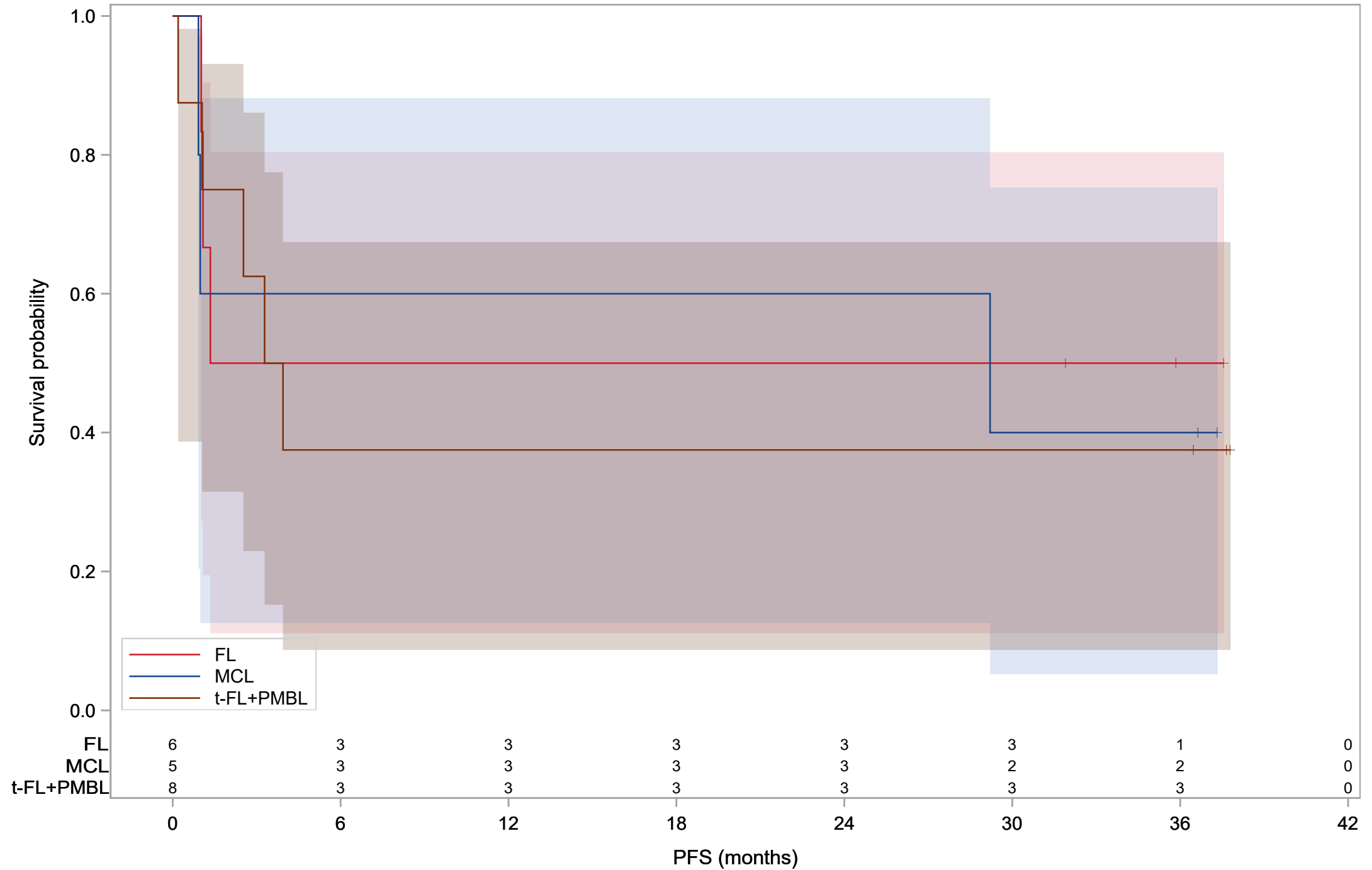
Duration of response since first CMR or PMR - Cohort 2 - FAS
With number of subjects at risk



No. of subjects	Event	Censored	Median survival (95% CI)
11	27.3 % (3)	72.7 % (8)	Not reached (2.2 ; NA)

Supplemental Figure 1. Progression-free survival according to histology

PFS since C1D1 of Glofitamab according to Diagnosis - Cohort 2 - FAS
with number of subjects at risk



	No. of subjects	Event	Censored	Median survival (95% CI)
FL	6	50 % (3)	50 % (3)	Not reached (1.0 ; NA)
MCL	5	60 % (3)	40 % (2)	29.2 (0.9 ; NA)
t-FL+PMBL	8	62.5 % (5)	37.5 % (3)	3.6 (0.2 ; NA)