Epcoritamab plus rituximab, dexamethasone, cytarabine, oxaliplatin/carboplatin induces deep and durable responses in transplant-eligible patients with relapsed or refractory diffuse large B-cell lymphoma: results from the EPCORE NHL-2 trial

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Abstract

The treatment of relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL) remains challenging, with inadequate responses to salvage chemoimmunotherapy limiting patients' ability to receive potentially curative treatments such as autologous stem cell transplantation (ASCT). Epcoritamab, a subcutaneous CD3×CD20 bispecific antibody, has demonstrated antitumor activity in R/R DLBCL as a monotherapy and in combination with chemotherapy. In arm 4 of the EPCORE® NHL-2 phase IB/II trial (ClinicalTrials.gov identifier: NCT04663347), transplant-eligible patients with CD20$^+$ R/R DLBCL received epcoritamab plus rituximab, dexamethasone, cytarabine, oxaliplatin/carboplatin (R-DHAX/C). Patients could continue epcoritamab until ASCT or progression. Twenty-nine patients received epcoritamab plus R-DHAX/C; 72% had stage IV disease; 66% had primary refractory disease. As of January 15, 2025 (median follow-up 40.4 months), the overall response rate (primary endpoint) was 79%, and complete response rate was 69%. Sixteen patients (55%) proceeded to ASCT and five remained on epcoritamab monotherapy. At 36 months, an estimated 70% of responses were ongoing, 59% of patients were progression-free, and 76% were alive. Common treatment-emergent adverse events (TEAE) were thrombocytopenia (90%), anemia (66%), and neutropenia (59%). Cytokine release syndrome occurred in 45% of patients; all were grade 1-2 and resolved after a median of 2 days. Immune effector cell-associated neurotoxicity syndrome occurred in one patient. No fatal TEAE or clinical tumor lysis syndrome were observed. Epcoritamab plus R-DHAX/C achieved deep, durable responses with manageable safety. Over half of patients proceeded to ASCT, a potentially curative treatment. These findings suggest the potential of epcoritamab combined with standard chemoimmunotherapy as an effective salvage treatment for patients with R/R DLBCL.

Introduction

Salvage chemoimmunotherapy followed by consolidation with high-dose therapy (HDT) and autologous stem cell transplantation (ASCT) is a standard second-line (2L) treatment for patients with diffuse large B-cell lymphoma (DLBCL) who experience relapse more than 12 months after initial therapy, and can be curative in this setting. Approximately 50% of HDT-ASCT-eligible patients undergo transplantation after initial salvage therapy and achieve disease remission, with an overall cure rate of up to 35%.[1] However, 40-60% of patients do not achieve an adequate response to salvage chemoimmunotherapy, which limits their ability to proceed to HDT-ASCT and leads to poor outcomes.[2-4] Patients with DLBCL treated with rituximab, dexamethasone, cytarabine, oxaliplatin/carboplatin (R-DHAX/C) have previously shown complete response (CR) rates of approximately 50%.[5] For other salvage chemoimmunotherapy regimens, such as dexamethasone, high-dose cytarabine, cisplatin (DHAP), dexamethasone, high-dose cytarabine, carboplatin (DHAC), ifosfamide, carboplatin, etoposide (ICE), gemcitabine, dexamethasone, cisplatin (GDP), and gemcitabine, oxaliplatin (GemOx), reported overall response (OR) rates ranged from 40% to 60%, even with the addition of rituximab.[6] Patients who achieve CR with salvage chemoimmunotherapy regimens may be able to proceed to HDT-ASCT, thereby achieving improved outcomes compared with patients who continue with chemoimmunotherapy.[7] Patients undergoing ASCT without achieving CR during salvage therapy experience shorter progression-free survival (PFS) and overall survival (OS) compared with those undergoing ASCT while in a CR.[8]

Chimeric antigen receptor (CAR) T-cell therapies, including lisocabtagene maraleucel (liso-cel) and axicabtagene ciloleucel (axi-cel), are approved for the treatment of patients with large B-cell lymphoma who have refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy, based on results from the phase III TRANSFORM and ZUMA-7 clinical trials.[9,10] CAR T-cell therapies have become the standard of care for patients who progress within 12 months of first-line (1L) therapy and have been associated with longer survival compared with salvage chemoimmunotherapy.[11] However, CAR T-cell therapy use is constrained by clinical and logistical challenges for physicians, patients, and care partners; based on survey results obtained between 2022 and 2024, only around 25% of eligible patients with large B-cell lymphoma received 2L CAR T-cell therapy in the US.[12] Treatment is typically delayed by the lengthy manufacturing process required before infusion, and access is limited to specialized treatment or academic centers.[13,14] Additional barriers include the need for bridging therapy, patient ineligibility, and high costs. Furthermore, CAR T-cell therapies are largely unavailable in many regions of the globe, with approvals currently limited to high- and middle-income countries.[15]

While CAR T-cell therapy is approved as second-line treatment for patients with R/R DLBCL who relapse within 12 months after first-line therapy, ASCT remains a curative option for patients with R/R DLBCL who relapse after 12 months and for those without access to CAR T-cell therapy.[14] Therefore, there is still a need for effective, accessible salvage regimens that improve transplant eligibility and enable more patients to proceed to ASCT.

Epcoritamab is a subcutaneous CD3×CD20 bispecific antibody that induces T-cell-mediated killing of CD20$^+$ malignant B cells and is approved for treatment of adult patients with R/R DLBCL, and DLBCL not otherwise specified (NOS) including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma (HGBCL; US only), after two or more lines of systemic therapy.[16-20] Given its distinct mechanism of action and manageable safety profile, epcoritamab is a promising candidate for combination with salvage chemoimmunotherapies.[20-24] Previously, epcoritamab plus R-GemOx demonstrated high OR (85%) and CR (61%) rates, and manageable safety, supporting the clinical benefit of combining epcoritamab with chemotherapy regimens in HDT-ASCT-ineligible patients with DLBCL who have received two or more lines of therapy.[25] Here, we report efficacy and safety results from arm 4 of the EPCORE NHL-2 trial, which evaluated epcoritamab plus R-DHAX/C in HDT-ASCT-eligible patients with R/R DLBCL.

Methods

Study design and patients

EPCORE NHL-2 (ClinicalTrials.gov identifier: NCT04663347) is a phase IB/II, open-label, multicenter, multicohort trial in patients with CD20$^+$ non-Hodgkin lymphoma. In arm 4, eligible patients were ≥18 years of age, had histologically confirmed CD20$^+$ DLBCL (including double-hit/triple-hit DLBCL, classified as high-grade B-cell lymphoma with *MYC* and *BCL2* and/or *BCL6* translocations), had R/R disease after one or more prior lines of therapy, were HDT-ASCT-eligible, had an Eastern Cooperative Oncology Group performance status of 0-2 and measurable disease by computed tomography – magnetic resonance imaging.

The study consisted of dose-escalation and dose-expansion parts. In the dose escalation, patients received 24 mg or 48 mg full doses of epcoritamab in the same schedule as in the dose expansion. In dose expansion, subcutaneous epcoritamab 48 mg was administered once weekly (QW) in 21-day cycles ([C]1-3) in combination with R-DHAX/C (rituximab 375 mg/m^2 intravenously [IV] every 3 weeks [Q3W]; dexamethasone 40 mg/day IV or orally on days 1-4; cytarabine 2 g/m^2 IV repeated after 12 hours Q3W; carboplatin for an area under the concentration curve of 5 mg/mL × min [Calvert formula] or oxaliplatin 100 mg/m^2 IV Q3W). Epcoritamab monotherapy continued QW in C4 (21-day

cycles), then in 28-day cycles (Q2W, C5-9; Q4W, C10+) until HDT-ASCT, progressive disease, or unacceptable toxicity. During C1, two step-up doses (0.16 mg on day 1 and 0.8 mg on day 8) followed by full 48 mg doses of epcoritamab were administered; patients were hospitalized for ≥24 hours after the first full dose. Patients received corticosteroid prophylaxis (prednisolone 100 mg orally or equivalent on days 1-4, days 8-11, and days 15-18 in C1, and days 1-4 in C2) for cytokine release syndrome (CRS).[23] Premedication with diphenhydramine 50 mg, acetaminophen 650-1000 mg, and prednisolone 100 mg orally (or equivalent) was mandatory up to the second full dose of epcoritamab. Patients with recurrent cases of grade ≥3 neutropenia were mandated to receive granulocyte colony-stimulating factor.

Endpoints

The primary endpoint was investigator-assessed OR rate (Lugano criteria).[26] Secondary endpoints included CR rate, time to response, time to CR, duration of response, duration of CR, PFS, OS, time to next anti-lymphoma therapy, adverse events (AE), serious AE, and AE of special interest.

Assessments

Tumor response was evaluated by fluorodeoxyglucose positron emission tomography – computed tomography every 6 weeks for the first 24 weeks, every 12 weeks through to week 48, and every 24 weeks thereafter, relative to the first day of any trial drug administration. The first on-treatment response assessment occurred at week 6.

AE were assessed from first treatment dose for a maximum of 60 days after the last dose of epcoritamab and 30 days after the last dose of standard-of-care treatment or start of a new line of lymphoma therapy. Serious AE were reported throughout the study; serious AE considered related to epcoritamab were reported continuously after the safety follow-up visit (>60 days after the last dose).

Statistical analysis

All analyses were descriptive and based on the full analysis set (patients who received ≥1 dose of study treatment); safety analyses were conducted in the safety population (same definition as full analysis set). OR and CR rates were summarized with 95% confidence intervals (95% CI) using the Clopper-Pearson method. Time-to-event endpoints were analyzed using Kaplan-Meier methods. Additional details are provided in the *Online Supplementary Methods*.

Ethics approval

The study was approved by the institutional review board or central ethics committee at each participating institution and was conducted according to the ethical principles that have their origin in the Declaration of Helsinki, the International Council for Harmonisation consolidated Guideline E6 for Good Clinical Practice, and applicable regulatory requirements.

Results

Study population and treatment exposure

Twenty-nine patients were enrolled between February and September 2021, and all were treated with epcoritamab plus R-DHAX/C. Three patients received epcoritamab 24 mg and 26 received epcoritamab 48 mg as the full dose across dose escalation and expansion. The median age was 58 years (range, 28-75); 83% (24/29) of patients were male at birth, 72% (21/29) had Ann Arbor stage IV disease, 66% (19/29) had primary refractory disease, and 83% (24/29) had extranodal involvement (Table 1). Five of 19 (26%) patients with available data had high-grade B-cell lymphoma with *MYC* and *BCL2* and/or *BCL6* rearrangements (double-hit/triple-hit lymphoma) per central laboratory analysis. The median number of prior line of therapies was 1 (range, 1-3), 76% (22/29) of patients had received one prior line of therapy, 83% (24/29) had progressed within 12 months of first-line therapy, and 10% (3/29) had received prior CAR T-cell therapy. As of the data cutoff (January 15, 2025), the median study follow-up was 40.4 months (range, 2.0+ to 45.5).

Among the 29 patients, 21 (72%) completed epcoritamab plus R-DHAX/C treatment per protocol (Figures 1 and 2). Of these, 16 patients proceeded to ASCT and five continued epcoritamab monotherapy. Reasons for continuing epcoritamab monotherapy and not proceeding to ASCT were patients' choice (3/5) and infectious AE (2/5). Among the eight (28%) patients who discontinued treatment, reasons for discontinuation were progressive disease (21%; 6/29) and AE (7%; 2/29). Six of the eight patients who discontinued trial treatment subsequently received CAR T-cell therapy; of these, two underwent allogenic stem cell transplantation. Four of the six patients who received CAR T-cell therapy had subsequent progressive disease.

Patients received a median of 4 (range, 1-41) cycles of epcoritamab, with a median relative dose intensity of 88% and a median epcoritamab treatment duration of 2.7 months (range, 0-39.4). The median number of R-DHAX/C cycles was 3 (range, 1-3). The median relative dose intensities were 98% for rituximab, 99% for oxaliplatin, 86% for carboplatin, and 93% for cytarabine. Among patients who proceeded to HDT-ASCT (N=16), the median number of R-DHAX/C cycles was 3 (range, 2-3) and the median number of epcoritamab cycles was 4 (range, 3-7). The median time from the last epcoritamab dose to HDT-ASCT was 14 days (range, 2-52). Among patients who stayed on epcoritamab (N=5), the median number of R-DHAX/C cycles was 3 (range, 1-3) and the median number of epcoritamab cycles was 24 (range, 10-41). Among patients who discontinued treatment due to other reasons (N=8), the median number of R-DHAX/C cycles was 2.5 (range, 1-3) and the median number of epcoritamab cycles was 3 (range, 1-4).

Efficacy

In the overall study population (N=29), the OR rate was

79% (23/29; 95% CI: 60.3-92.0) and the CR rate was 69% (20/29; 95% CI: 49.2-84.7). Three (10%) patients had a partial response as their best response, and stable disease and progressive disease were observed as best responses in two (7%) patients each. Two patients were not evaluable and classified as non-responders, as they discontinued the trial prior to their first lymphoma assessment. At the first protocol-scheduled response assessment at week 6, the OR rate was 72% (21/29), including a CR rate of 45% (13/29). Response rates were consistently high among prespecified subgroups. Among patients with primary refractory disease (N=19), the OR rate was 68% (95% CI: 43-87) and the CR rate was 53% (95% CI: 29-76). OR and CR rates in patients who relapsed within 12 months of initial therapy (N=24) were 75% (95% CI: 53-90) and 63% (95% CI: 41-81), respectively. Among patients who relapsed after 12 months of initial therapy (N=5), OR and CR rates were both 100% (95% CI: 48-100). In those who had received one prior line of therapy (N=22), the OR rate was 77% (95% CI: 55-92) and the CR rate was 68% (95% CI: 45-86).

Overall, the median time to response and time to CR were 1.4 months (range, 1.2-3.9) and 1.5 months (range, 1.2-15.5), respectively. The median duration of response, duration of CR, OS (Figures 3 and 4), and time to next anti-lymphoma therapy were not reached; the median PFS was 38.7 months (95% CI: 11.5-not reached). At 36 months, an estimated

Table 1. Baseline demographic and clinical characteristics.

Characteristics	All patients N=29
Median age, years (range) <65, N (%)	58 (28-75) 21 (72.4)
Male at birth, N (%)	24 (82.8)
Race, N (%) Asian Black or African-American White Not reported	 1 (3.4) 1 (3.4) 25 (86.2) 2 (6.9)
ECOG PS, N (%) 0 1 2	 11 (37.9) 18 (62.1) 0
Disease type at study entry, N (%) DLBCL FL grade 3B	 28 (96.6) 1 (3.4)
DLBCL type, N (%)[a] *De novo* Transformed	 18 (62.1) 11 (37.9)
Cell of origin, N (%) GCB Non-GCB/ABC Unknown/missing	 15 (51.7) 10 (34.5) 4 (13.8)
Extranodal disease, N (%)[b]	24 (82.8)
DH/TH status with chromosomal alteration per central laboratory, N/N (%)	5/19 (26.3)
Ann Arbor stage, N (%) II III IV	 4 (13.8) 4 (13.8) 21 (72.4)
IPI, N (%) 0-2 3 4-5	 13 (44.8) 10 (34.5) 6 (20.7)
Bulky disease status, N (%) <7 cm ≥7 cm	 22 (75.9) 7 (24.1)
Primary refractory disease, N (%)	19 (65.5)
N of prior lines of anti-lymphoma therapy, median (range)	1.0 (1-3)
Prior lines of anti-lymphoma therapy, N (%) 1 2 3	 22 (75.9) 5 (17.2)[c] 2 (6.9)[d]
Prior CAR T-cell therapy, N (%)	3 (10.3)
Time from end of last anti-lymphoma therapy to first dose, months, median (range)	6.34 (0.6-48.8)
First-line response status, N (%) Refractory No response Relapsed within 6 months after therapy Relapsed Progressed within 12 months after therapy	 19 (65.5) 4 (13.8) 15 (51.7) 10 (34.5) 24 (82.8)
Best response to last line of therapy, N (%)[e] Complete response Partial response Stable disease Progressive disease	 18 (62.1) 7 (24.1) 1 (3.4) 2 (6.9)
Refractory to anti-CD20, N (%)	19 (65.5)

[a]Subtypes of diffuse large B-cell lymphoma (DLBCL) include: DLBCL not otherwise specified, double-hit and triple-hit DLBCL (high-grade B-cell lymphoma with *MYC* and *BCL2* and/or *BCL6* translocations), follicular lymphoma grade 3B, and T-cell/histiocyte-rich DLBCL. [b]Assessment based on non-nodal sites. [c]Two patients had received chimeric antigen receptor (CAR) T-cell therapy, two patients (both had transformed DLBCL) received R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisolone), and one patient received R-GDP (rituximab, gemcitabine, dexamethasone, cisplatin) as their last treatment. [d]One patient had received R-CHOP, R-DHAP (rituximab, dexamethasone, cytarabine, cisplatin), and rituximab-bendamustine for prior follicular lymphoma and one patient with transformed DLBCL had received R-CHOP, R-GDP, and CAR T-cell therapy. [e]Two additional patients (7%) discontinued due to adverse events before their first tumor assessment. ECOG PS: Eastern Cooperative Oncology Group performance status; FL: follicular lymphoma; GCB: germinal center B-cell; ABC: activated B-cell; DH/TH: double-hit/triple-hit; IPI: International Prognostic Index.

70% of responders remained in response, 71% of CR were ongoing, 59% of patients were progression-free, and 76% were alive. Seven of the eight patients who discontinued epcoritamab plus R-DHAX/C treatment had died by the

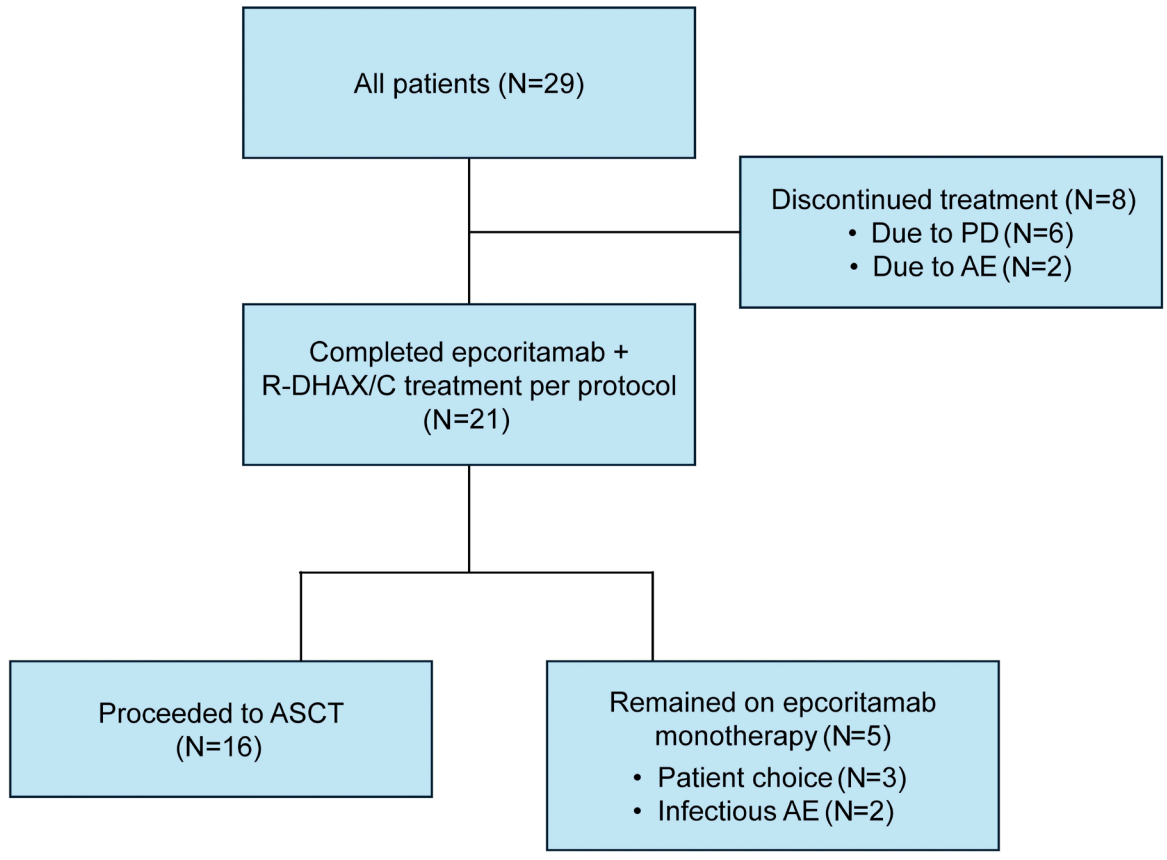


Figure 1. Patient flow diagram. PD: progressive disease; AE: adverse event; R-DHAX/C: rituximab, dexamethasone, cytarabine, oxaliplatin/carboplatin; ASCT: autologous stem cell transplantation.

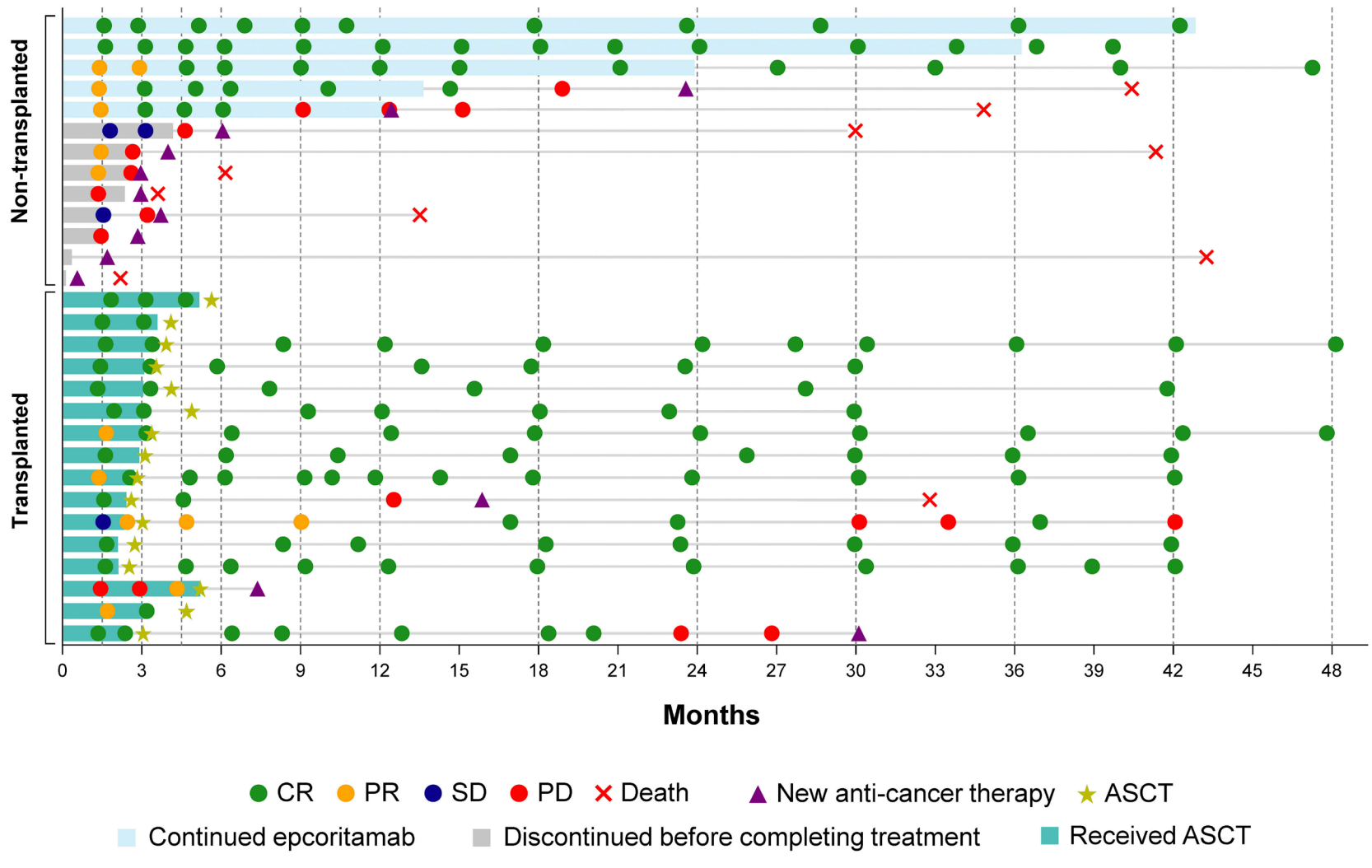


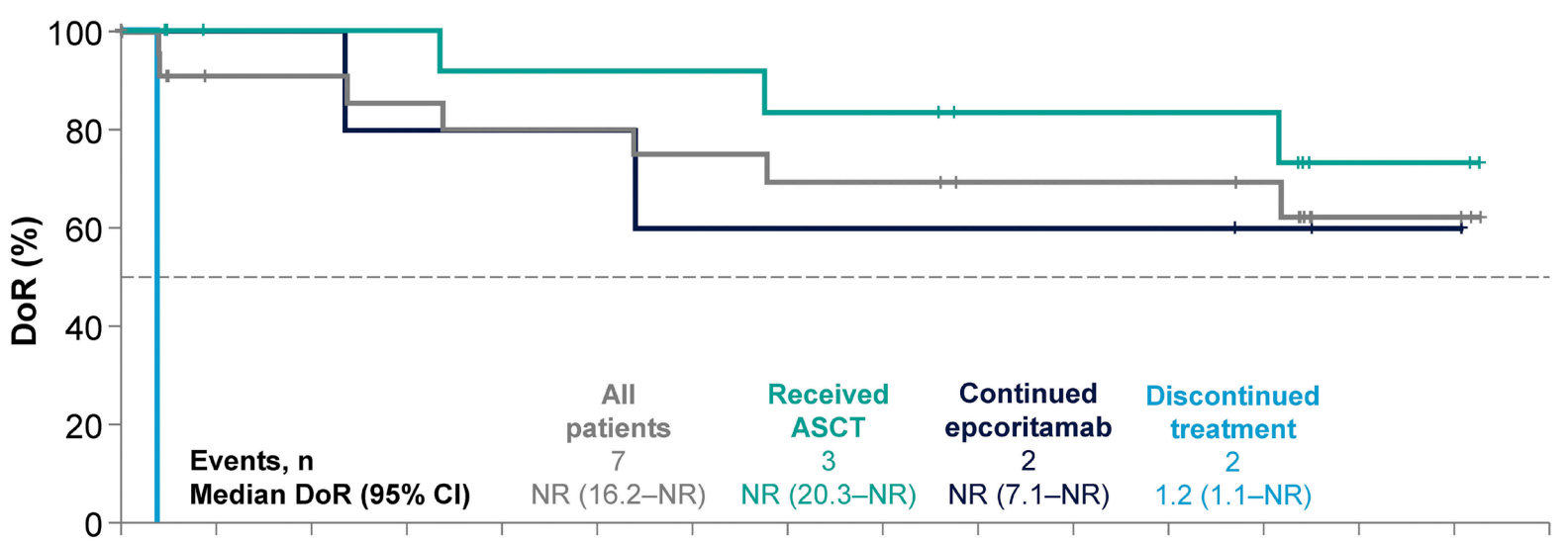
Figure 2. Responses by investigator assessment per Lugano criteria over time in patients receiving epcoritamab plus R-DHAX/C (full analysis set). CR: complete response; PR: partial response; SD: stable disease; PD: progressive disease; ASCT: autologous stem cell transplantation; R-DHAX/C: rituximab, dexamethasone, cytarabine, oxaliplatin/carboplatin.

data cutoff, three of whom had reportedly died due to progressive disease.

Among the 16 patients who proceeded to ASCT, 14 (88%) had a CR and two (13%) had a partial response at the time of transplant (Figure 2). One patient in partial response converted to a CR after HDT-ASCT, resulting in a post-transplant CR rate of 94%. Seven of the 16 patients (44%) received plerixafor for mobilization for stem-cell harvest, of whom one (6%) did not mobilize until a second attempt with granulocyte colony-stimulating factor, and four (25%) underwent apheresis over 2 days, compared to 1 day for all other patients. Consistent with what was observed in the overall population, the median duration of response, duration of CR, PFS, OS (Figures 3 and 4), and time to next anti-lymphoma therapy were not reached in patients who proceeded to ASCT. At 36 months, an estimated 83% of patients who received HDT-ASCT remained in remission and 75% remained in CR.

Five (17%) patients continued with epcoritamab treatment and did not undergo ASCT, and all five achieved a CR: three during the combination treatment, and two had a partial response with combination treatment and converted to a CR after staying on epcoritamab monotherapy. At the data cutoff, all five patients had discontinued treatment due to AE (N=2), progressive disease (N=1), and by patients' request (N=2). Three patients remained in CR (durations,

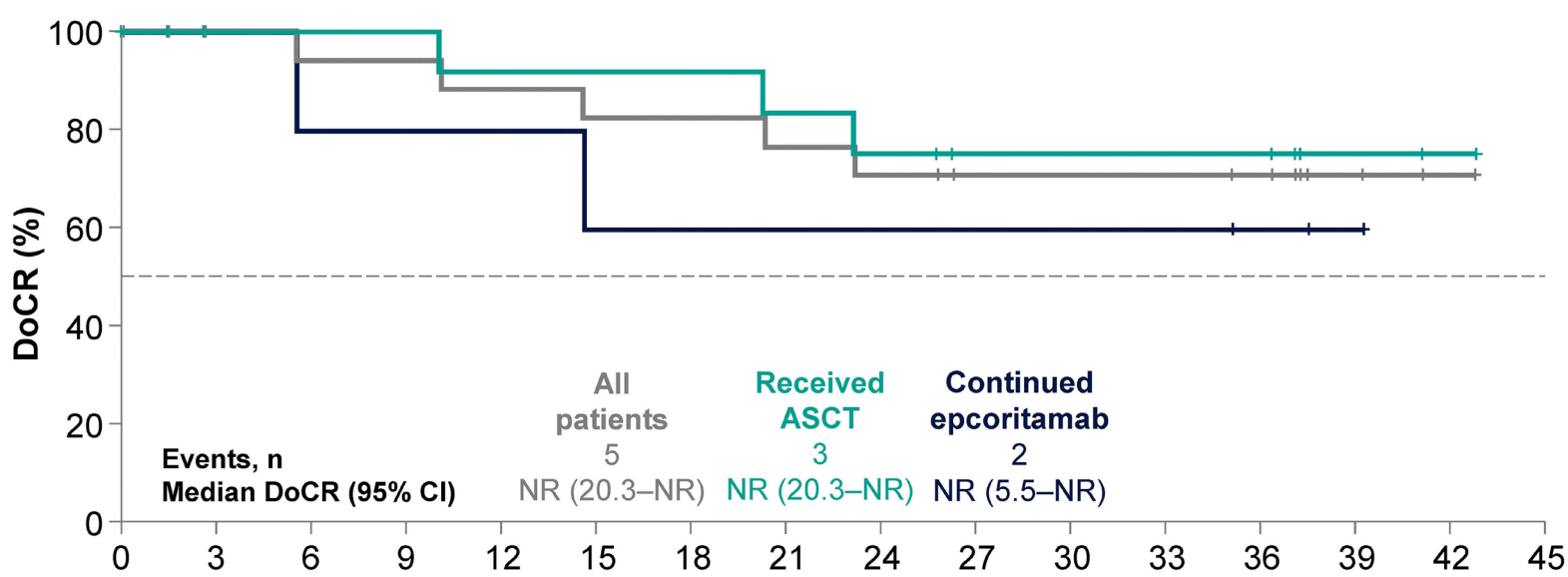
A



Patients at risk

	Months															
All patients	23	17	17	16	15	15	14	13	13	11	11	11	10	3	3	0
Received ASCT	16	12	12	12	11	11	11	10	10	8	8	8	8	2	2	0
Continued epcoritamab	5	5	5	4	4	4	3	3	3	3	3	3	2	1	1	0
Discontinued treatment	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

B



Patients at risk

	Months															
All patients	20	17	16	16	15	14	14	13	12	10	10	10	9	3	1	0
Received ASCT	15	12	12	12	11	11	11	10	9	7	7	7	7	2	1	0
Continued epcoritamab	5	5	4	4	4	3	3	3	3	3	3	3	2	1	0	0

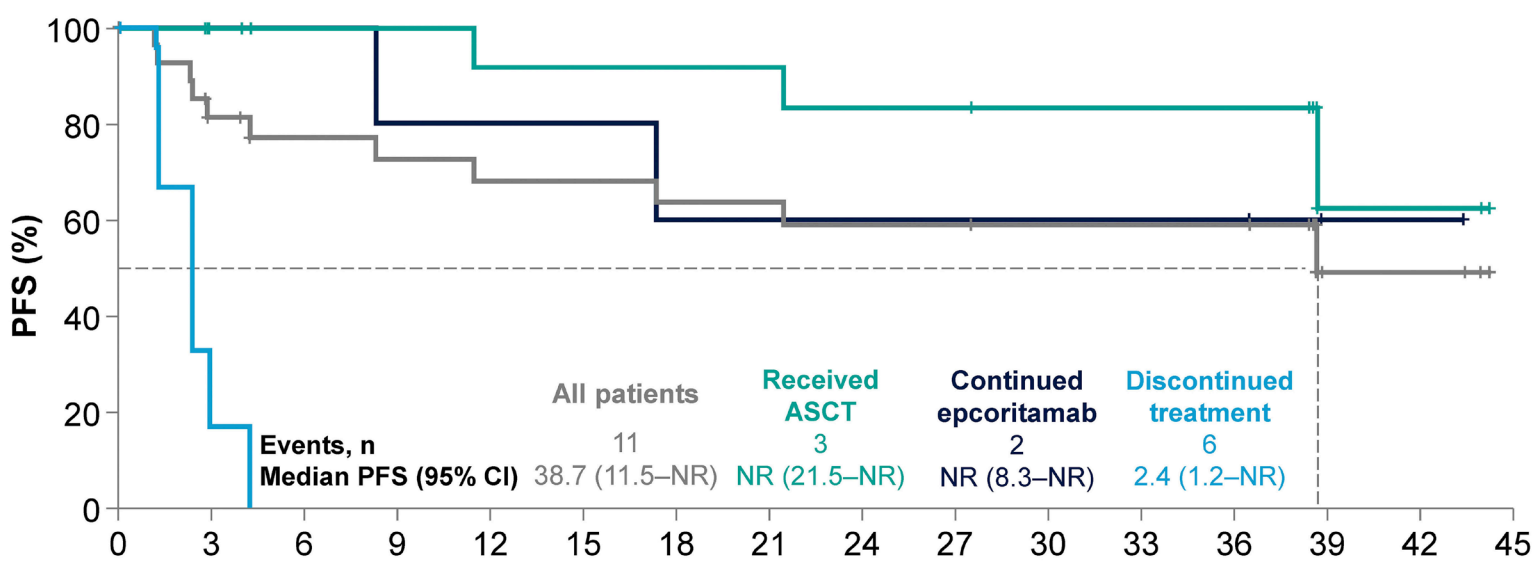
Figure 3. Durability of responses in patients receiving epcoritamab plus R-DHAX/C. (A) Duration of response for all patients, patients who proceeded to autologous stem cell transplantation (ASCT), patients who stayed on epcoritamab, and patients who discontinued treatment. (B) Duration of complete response for all patients, patients who proceeded to ASCT, and patients who stayed on epcoritamab. R-DHAX/C: rituximab, dexamethasone, cytarabine, oxaliplatin/carboplatin; DoR: duration of response; CI: confidence interval; NR: not reached; DoCR: duration of complete response.

35.1+, 37.5+, and 42.2+ months), and two had progressed after remaining in CR for 7.1 months and 16.2 months.

Safety

All 29 patients had a treatment-emergent AE, with grade 3 or 4 events reported in 97% (28/29) of patients and serious AE in 52% (15/29). The most common treatment-emergent AE were thrombocytopenia (90%; 26/29), anemia (66%; 19/29), neutropenia (59%; 17/29), and nausea (52%; 15/29) (Table 2). CRS occurred in 45% (13/29) of patients; all events were low grade (grade 1: 34% [10/29], grade 2: 10% [3/29]), and fever was the most common symptom (100% [13/13]), followed by hypotension (15% [2/13]) and hypoxia (15% [2/13]). CRS was most common after the first full dose (33% [9/27]). All CRS events resolved, and the median time to resolution was 2 days (range, 1-7). No patients discontinued treatment due to CRS. One (3%) patient had grade 2 immune effector cell-associated neurotoxicity syndrome, which led to epcoritamab discontinuation and which resolved within 37 days. Febrile neutropenia was reported in 17% (5/29) of patients. Overall, 16 (55%) patients received granulocyte-colony stimulating factor as prophylaxis. Grade 1 peripheral neuropathy was reported in 10% (3/29) of patients, and there were no events of clinical

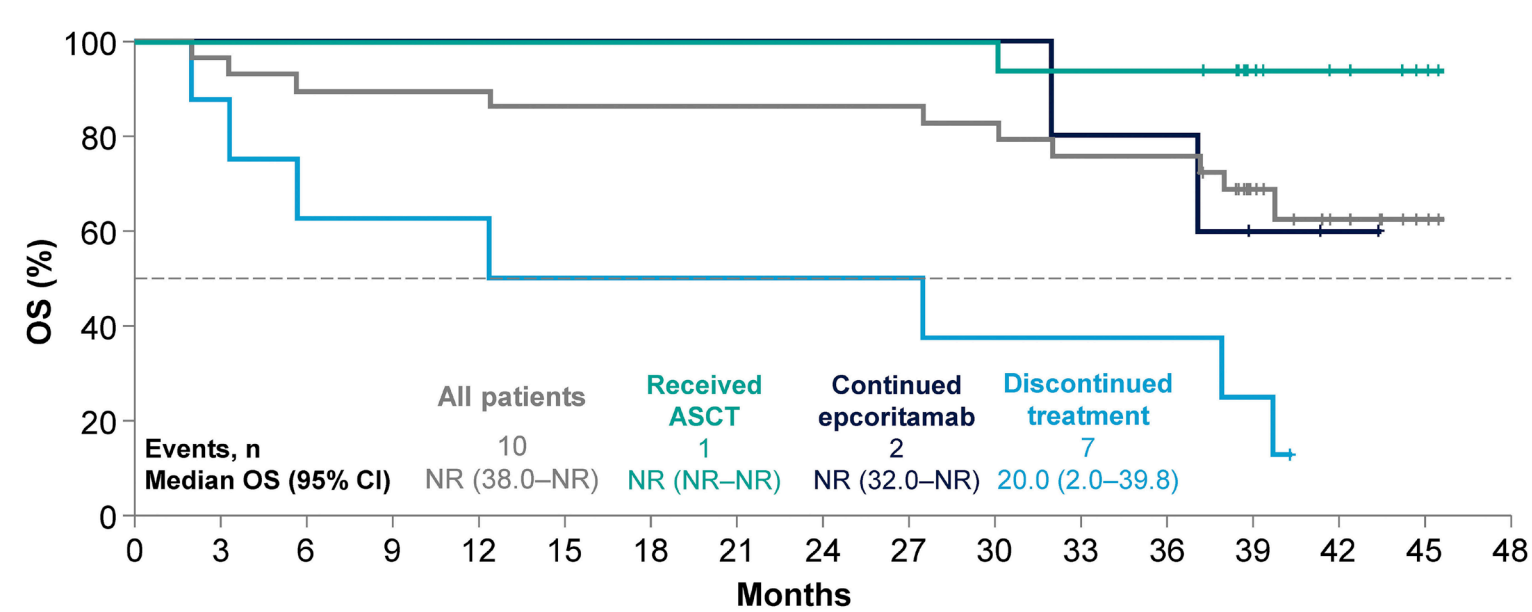
A



Patients at risk

All patients	29	20	17	16	15	15	14	14	13	13	11	11	11	3	3	0
Received ASCT	16	14	12	12	11	11	11	11	10	10	8	8	8	2	2	0
Continued epcoritamab	5	5	5	4	4	4	3	3	3	3	3	3	3	1	1	0
Discontinued treatment	8	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0

B



Patients at risk

All patients	29	28	26	26	26	25	25	25	25	25	24	22	22	13	7	2	0
Received ASCT	16	16	16	16	16	16	16	16	16	16	16	15	15	9	6	2	0
Continued epcoritamab	5	5	5	5	5	5	5	5	5	5	5	4	4	2	1	0	0
Discontinued treatment	8	7	5	5	5	4	4	4	4	4	3	3	3	2	0	0	0

Figure 4. Survival outcomes in patients receiving epcoritamab plus R-DHAX/C. (A) Progression-free survival for all patients, patients who proceeded to autologous stem cell transplantation (ASCT), patients who stayed on epcoritamab, and patients who discontinued treatment. (B) Overall survival for all patients, patients who proceeded to ASCT, patients who stayed on epcoritamab, and patients who discontinued treatment. PFS: progression-free survival; CI: confidence interval; NR: not reached; OS: overall survival; R-DHAX/C: rituximab, dexamethasone, cytarabine, oxaliplatin/carboplatin.

tumor lysis syndrome.

Infections of any grade were reported in 41% (12/29) of patients, with grade 3 or 4 infections in 17% (5/29) and 7% (2/29), respectively. Infections were mostly viral (21%, 6/29; COVID-19 [14%; 4/29], cytomegalovirus colitis, viral gastroenteritis, oral herpes, and herpes zoster [3% each; 1/29]), followed by bacterial infections (14%, 4/29; cellulitis, *Escherichia* urinary tract infection, folliculitis, lower respiratory tract infection, pseudomonal pneumonia, Staphylococcal skin infection, Streptococcal endocarditis [3% each; 1/29]), and fungal infections (14%, 4/29; 1 pulmonary aspergillosis [after ASCT; 3%] and 3 superficial fungal infections [oral candidiasis, genital infection, skin infection; 3% each]). No deaths occurred due to infection.

Treatment-emergent AE led to epcoritamab dose delays in 59% (17/29) of patients. Three patients discontinued epcoritamab due to treatment-emergent AE; two discontinued due to treatment-emergent AE (immune effector cell-associated neurotoxicity syndrome and Guillain–Barré syndrome) during co-administration with R-DHAX/C, and another patient who remained on epcoritamab monotherapy discontinued due to respiratory tract infection (*Online Supplementary Table S1*). No fatal treatment-emergent AE were reported. No transplant-related deaths were reported.

Discussion

HDT followed by ASCT remains a curative option for patients with R/R DLBCL in the second-line setting, with treatment failure more than 12 months after first-line therapy. However, the lack of response to salvage chemoimmunotherapy continues to limit transplant applicability. Thus, effective and widely available salvage regimens are needed to improve response rates and to enable more patients to proceed to ASCT. In this study, epcoritamab combined with R-DHAX/C as salvage therapy led to a notable increase in response rates, with an OR rate of 79%, compared with historic response rates of 40-60% with chemoimmunotherapy/R-DHAX/C alone.[2,29,30] An encouraging CR rate of 69% was observed in the overall population, and responses occurred early, with many observed at the first assessment. Overall, 55% of patients proceeded to ASCT, and the majority (83%) of patients with a response remained in response at 3 years.

While sample sizes are small, deep and durable responses were observed across subgroups, including in patients with historically poor outcomes (e.g., those with primary refractory disease or early relapse following first-line therapy), suggesting promising efficacy in challenging-to-treat patients. Of particular interest, responses were durable among the five patients who did not proceed to ASCT and continued epcoritamab monotherapy; three patients remained in CR at data cutoff. After a median follow-up of 40.4 months, the median duration of response, PFS, and OS were not reached in both the transplanted and non-transplanted subgroups. These results suggest that the addition of epcoritamab to salvage chemoimmunotherapy may improve response rates and transplant eligibility, while potentially offering durable disease control in patients not proceeding to ASCT.

Combinations of a bispecific antibody plus chemoimmunotherapy regimens have demonstrated promise as effective treatment options in the setting of transplant-eligible and transplant-ineligible patients who have received two or more lines of treatmebt. The combination of epcoritamab with GemOx assessed in the EPCORE NHL-2 trial led to high OR and CR rates of 85% and 61%, respectively, in patients

Table 2. Treatment-emergent adverse events.

Treatment-emergent adverse events	All patients N=29
TEAE, N (%)	
Any grade	29 (100)
Grade 3/4	28 (96.6)
Grade 5	0
Serious TEAE, N (%)	15 (51.7)
TEAE leading to any trial drug discontinuation, N (%)	4 (13.8)
TEAE leading to epcoritamab discontinuation, N (%)	3 (10.3)
TEAE leading to dose delay, N (%)	17 (58.6)
TEAE leading to epcoritamab dose delay, N (%)	17 (58.6)
Fatal TEAE, N (%)	0
Most common TEAE in ≥20% of patients, N (%)	
Thrombocytopenia[a]	26 (89.7)
Anemia[b]	19 (65.5)
Neutropenia[c]	17 (58.6)
Nausea	15 (51.7)
Cytokine release syndrome	13 (44.8)
Fatigue	11 (37.9)
Diarrhea	10 (34.5)
Headache	8 (27.6)
Constipation	7 (24.1)
Aspartate aminotransferase increased	6 (20.7)
Cough	6 (20.7)
Pyrexia	6 (20.7)
Serious infections[d]	6 (20.7)

Adverse events were coded using the Medical Dictionary for Regulatory Activities (MedDRA) and graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events, version 5.0.[27] Treatment-emergent adverse events (TEAE) were reported up to 60 days after the last dose of epcoritamab. Cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome were graded using American Society for Transplantation and Cellular Therapy consensus grading criteria.[28] [a]Thrombocytopenia includes hematopoietic thrombocytopenia using a standardized MedDRA query narrow search. [b]Neutropenia includes neutropenia or neutrophil count decrease. [c]Anemia includes anemia, hematocrit decrease, hemoglobin decrease, and red blood cell count decrease. [d]Serious infections include serious TEAE in the System Organ Class of infections and infestations. In total, six patients had serious infections (pneumonia [N=3], bronchitis, pulmonary aspergillosis, COVID-19, cellulitis, *Escherichia* urinary tract infection, gastroenteritis viral, periodontitis, sepsis, sinusitis, streptococcal endocarditis, and upper respiratory tract infection [N=1 each]).

with ASCT-ineligible R/R DLBCL (median follow-up, 13.2 months).[25] Compared to epcoritamab and GemOx, which led to a median PFS of 11.2 months, a longer median PFS of 38.7 months was observed in the present study, which may be reflective of the transplant-eligible population.[25] Similarly, an OR rate of 68% was observed in patients who received glofitamab plus GemOx in the STARGLO trial (median follow-up, 20.7 months),[30] and preliminary results from the GO43693 trial suggest that glofitamab plus R-ICE yields an OR rate of 78%.[31] However, there remains a need for salvage regimens capable of inducing rapid, deep responses enabling HDT-ASCT. Epcoritamab in combination with other salvage chemoimmunotherapy regimens, such as R-ICE and GDP, have also achieved high response and transplant rates. Epcoritamab plus R-ICE resulted in an OR rate of 87%, with 65% of patients proceeding to HDT-ASCT,[32] while epcoritamab plus GDP led to an OR rate of 79%.[33] Collectively, these findings underscore the potential of bispecific antibody and chemoimmunotherapy combinations in R/R DLBCL.

The proportion of patients who proceeded to ASCT in this study was similar to historic rates, such as that in the CORAL study, in which 50-54% of patients proceeded to ASCT.[2] While 55% (16/29) of patients proceeded to ASCT following epcoritamab plus R-DHAX/C, an additional five patients remained on epcoritamab monotherapy due to their own choice or an AE; therefore, 72% (21/29) of patients benefited from the study treatment. Notably, this cohort of patients represented a challenging-to-treat population, with 83% of patients progressing within 12 months of prior therapy, 10% receiving prior CAR T-cell therapy, and 26% harboring double-hit or triple-hit lymphoma, features that are typically associated with poor outcomes.[1] Additionally, the higher CR rate achieved in the current study (69%) and 3-year PFS (59%) compared to the CORAL trial (48-53% CR rate, 37% 3-year event-free survival) highlights the importance of increasing CR rates prior to ASCT, often resulting in improved long-term outcomes.[2,8]

Our findings should be viewed in the context of other contemporary trials evaluating second-line treatment strategies for R/R DLBCL, particularly with the advent of CAR T-cell therapies. The current study enrolled patients prior to the 2022 approval of axi-cel and liso-cel CAR T-cell therapies for second-line treatment of R/R DLBCL in 2022.[34,35] The ZUMA-7 trial has since compared investigator-selected standard-of-care chemoimmunotherapy followed by HDT-ASCT *versus* CAR T-cell therapy (axi-cel).[10] At a median follow-up of 24.9 months, the CR rate was 65% in the axi-cel group and 32% in the standard-of-care group; 36% of patients assigned to standard of care proceeded to ASCT and 49% did not receive ASCT due to progressive or stable disease. The estimated OS at 4 years was 55% with axi-cel and 46% with standard of care; the estimated 4-year PFS rate was 42% with axi-cel *versus* 24% with standard of care.[36] The TRANSFORM trial compared standard of care (R-DHAP, R-ICE, or R-GDP plus ASCT) with liso-cel.[9] At a median follow-up of 33.9 months, the CR rates were 74% in the liso-cel group and 43% in the standard-of-care group; 47% of patients assigned to standard of care proceeded to ASCT.[37] At 36 months, OS rates were higher for liso-cel (63%) compared with standard of care (52%); 36-month PFS rates were 51% for liso-cel and 27% for standard of care.[37] While CAR T-cell therapy is a proven effective treatment for patients who progress within 12 months of first-line therapy, in the present study, patients with challenging-to-treat disease (66% primary refractory, 26% with double-hit/triple-hit lymphoma, and 10% with prior CAR T-cell therapy) achieved a promising OR rate of 79% with bispecific antibody treatment combined with platinum-based salvage chemoimmunotherapy followed by ASCT. This suggests that HDT-ASCT may remain a viable treatment option in patients with early progression when CAR T-cell therapy is not feasible or available. Moreover, while CAR T-cell therapies are now standard of care for patients with early progression, there is an ongoing need for effective treatment options for patients with later relapse. As ASCT is associated with improved long-term survival over salvage chemoimmunotherapy alone in patients with late relapses, increasing the number of patients who can undergo HDT-ASCT still represents an attractive strategy in this setting.[38] Additionally, achieving CR prior to ASCT can lead to improved long-term outcomes, as prior studies have noted that patients who proceed to ASCT without achieving CR often have shorter survival and poorer outcomes.[2,8]

The safety profile of epcoritamab plus R-DHAX/C was manageable and aligned with the known effects of the individual agents and no new safety signals emerged. CRS events were predictable (occurring most often after the first full dose), low grade (grade 1-2), and resolved without treatment discontinuation within a median of 2 days. Infections were generally viral. No treatment-related deaths occurred.

Among patients who received ASCT, seven out of 16 (44%) required plerixafor. Plerixafor use was not protocol-mandated and was administered at investigators' discretion, typically in patients with poor initial mobilization. Mobilization practices were not standardized across participating sites, and institutional variation in thresholds for introducing plerixafor may have contributed to the frequency observed. Given the small sample size, the impact of the treatment regimen on stem-cell mobilization or plerixafor requirements remains unknown. Importantly, all patients were successfully mobilized, and no patient in this study failed to proceed to ASCT due to mobilization failure.

This study has several strengths, including enrollment of a DLBCL population of patients who had received two or more lines of therapy with features indicative of poor prognosis, a setting in which effective salvage treatment options remain limited. The extended median follow-up (40.4 months) allowed for meaningful evaluation of long-term outcomes, including durability of responses and

survival outcomes. The analysis across transplanted and non-transplanted cohorts, reflecting real-world clinical decision-making, suggested the versatility of epcoritamab both as part of a chemoimmunotherapy regimen or as monotherapy. Encouraging results were seen in patients with challenging-to-treat primary refractory disease. Further investigation is warranted to determine the optimal placement of bispecific antibody therapy combined with salvage chemoimmunotherapy and HDT-ASCT in the treatment paradigm.

However, study limitations should also be acknowledged, including the single-arm design, limited sample size (thereby resulting in wide confidence intervals), and lack of power to differentiate the relative contributions of epcoritamab *versus* chemoimmunotherapy or isolate the contribution of ASCT. Additionally, because the study enrolled patients prior to the second-line approval of CAR T-cell therapies,[35,36] comparisons with more recent standards are limited.

In summary, epcoritamab plus R-DHAX/C delivered high response rates in this transplant-eligible patient population with R/R DLBCL who had received two or more lines of treatment. Durable responses were observed in both transplanted and non-transplanted patients, although interpretation of outcomes in the latter group is limited by the small sample size. Despite the single-arm design, these results support the potential benefit of adding epcoritamab to salvage therapy regimens and warrant further evaluation in larger, controlled studies.

Disclosures

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Contributions

PA, YHK, DM, RC, TP, SdV, MN, FO, P-OA, JB, CYC, PGP, MH, JMJ, DL, KML, GM, and LF were study investigators, provided patients or study materials, and collected and assembled data. LW, JM, KO-B, and MR prepared and analyzed the data. All authors interpreted the data, prepared the manuscript, participated in critical review and revision of the manuscript, and provided approval of the manuscript for submission.

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Data-sharing statement

Deidentified individual participant data collected during the trial will not be available upon request for further analyses by external independent researchers. Aggregated clinical trial data from the trial is provided via publicly accessible study registries/databases as required by law. For more information, please contact ClinicalTrials@genmab.com.

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