ABCL - 619

Epcoritamab + Chemoimmunotherapy in Patients With Relapsed/Refractory Large B-Cell Lymphoma Eligible for Autologous Stem Cell Transplant: Pooled Results From Arms 4 and 10 of EPCORE NHL-2

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Objective

- To report a pooled analysis of efficacy and safety data from Arms 4 (epcoritamab + R-DHAX) and 10 (epcoritamab + R-ICE) of the EPCORE NHL-2 trial in ASCT-eligible patients with R/R LBCL

Conclusions

- Epcoritamab plus CIT achieved high CR rates, increasing the proportion of patients proceeding to ASCT compared with historical rates
  - Response rates were consistently high in 2L patients (ORR, 84%), including those who progressed < 12 months of 1L treatment (ORR, 81%)
  - Sustained responses were observed regardless of consolidation (ASCT or epcoritamab monotherapy)
- For patients who did not proceed to transplant, epcoritamab maintenance improved long-term outcomes and prolonged survival, offering a viable non-transplant option
- Safety was consistent with the known safety profiles of the individual agents
- The results from this novel, pooled analysis continue to show that adding epcoritamab to CIT as salvage therapy increases the proportion of patients who respond to treatment and proceed to ASCT, a potentially curative therapy

Acknowledgments

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Abbreviations

ASCT, autologous stem cell transplantation; AUC, area under the curve; C, cycle; CIT, chemoimmunotherapy; CRS, cytokine release syndrome; D, day; DH, double-hit; HDT, high-dose therapy; HGBCL, high-grade B-cell lymphoma; MZL, marginal zone lymphoma; NOS, not otherwise specified; NR, not reached; ORR, overall response rate; R-DHAX/C, rituximab plus dexamethasone, cytarabine, and oxaliplatin/carboplatin; R-ICE, rituximab plus ifosfamide, carboplatin, and etoposide; TH, triple-hit.

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Introduction

- For patients with R/R DLBCL, salvage CIT followed by consolidation with HDT and ASCT is potentially curative, but current strategies fail to induce adequate responses in ~40–60% of patients, limiting transplant eligibility and leading to poor outcomes[1–5]
- CAR T cell therapy remains the standard of care in the 2L setting for patients with early relapse (< 12 months of 1L treatment),[6] but its use is limited by eligibility, accessibility, and cost considerations[7]
  - ORR/CR rates reported with CAR T cell therapy in the ZUMA-1 (axicabtagene ciloleucel) and TRANSFORM (lisocabtagene maraleucel) trials were 83%/58% and 87%/74%, respectively[8,9]
- There is a critical need for regimens that increase the response rates of salvage chemotherapy and facilitate a patient's ability to proceed to ASCT, a curative therapy
- In Arms 4 and 10 of the phase 1b/2 EPCORE NHL-2 trial (NCT04663347), combining CIT with epcoritamab, a subcutaneous CD3×CD20 bispecific antibody, was associated with high response rates in ASCT-eligible patients with R/R LBCL[10,11]

Methods

EPCORE® NHL-2 Arm 4 and 10 Study Design

Key inclusion criteria (both arms):

- CD20+ R/R DLBCL[a]
  - DLBCL, NOS
  - T-cell/histiocyte-rich LBCL
  - DH/TH DLBCL[b]
  - FL grade 3B
- ECOG PS 0–2
- R/R to ≥ 1 prior therapy
- Eligible for HDT-ASCT

Data cutoffs:
Arm 4: January 15, 2025
Arm 10: December 18, 2024

Epcoritamab + R-DHAX/C (Arm 4)

Agent	C1–3	C4	C5–9	C10+
Epcoritamab SC 24 mg or 48 mg[c]	QW	QW	Q2W	Q4W[f]
Rituximab IV 375 mg/m²	Q3W			
Prednisolone 100 mg PO (or PO/IV corticosteroid equivalent)				
Cytarabine[e] IV 2 g/m²				
Oxaliplatin IV 100 mg/m² or carboplatin IV AUC = 5 mg/mL × min				

Epcoritamab + R-ICE (Arm 10)

Agent	C1–3	C4	C5–9	C10+
Epcoritamab SC 24 mg or 48 mg[c]	QW	QW	Q2W	Q4W[f]
Rituximab IV 375 mg/m²	Q3W			
Ifosfamide[e] IV 5 g/m²/24 hr	D2 each cycle			
Carboplatin[e] IV AUC = 5 mg/mL × min				
Etoposide[e] IV 100 mg/m²	D1–3 each cycle			

- At end of combination treatment, patients could proceed to ASCT or remain on epcoritamab monotherapy
- **Primary endpoint:** ORR per investigator assessment based on Lugano criteria[12,i]
- **Key secondary endpoints:** CR rate, DOR, DOCR, PFS, OS, and safety

NCT04663347. [a]De novo or histologically transformed from FL or nodal MZL. [b]Classified as HGBCL, with *MYC* and *BCL2* and/or *BCL6* translocations. [c]Patients received epcoritamab with 2 step-up doses (0.16 mg and 0.8 mg) before the first full epcoritamab dose, and corticosteroid prophylaxis to mitigate CRS. C1–4 were 21 days (epcoritamab + R-DHAX/C or epcoritamab + R-ICE). Subsequent cycles of epcoritamab were 28 days. [d]Until new antilymphoma therapy (including HDT for ASCT) or disease progression or unacceptable toxicity. [e]Infusion usually over 3 hr, repeated after 12 hr; infusions will extend into the next day. [f]Given with mesna; mesna can also be given PO 2 and 6 hr after ifosfamide. [g]Max 800; given over 1 hr. [h]Given over 30 min to 1 hr. [i]Tumor response was evaluated by PET-CT. For Arm 4, imaging was performed every 6 weeks for the first 24 weeks, every 12 weeks through week 48, and then every 24 weeks, until disease progression. For Arm 10, imaging was performed at week 9, week 18, week 24, and then every 24 weeks, until disease progression.

Results

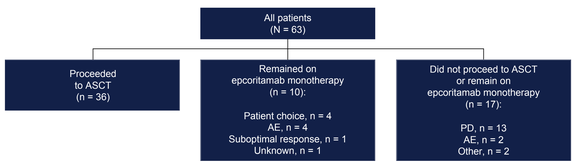
Baseline Characteristics

	Epcoritamab + CIT (N = 63)[a]
Median age, years (range)	61 (28–77)
Male sex at birth, n (%)	43 (68)
ECOG PS, n (%)	
0	26 (41)
1	37 (59)
IPI score, n (%)	
0–2	34 (54)
3	18 (29)
4–5	11 (17)
Ann Arbor stage, n (%)	
III–IV	45 (71)
Bulky disease (≥ 7 cm), n (%)	20 (32)
Chromosomal alterations per central lab,[b,c] n/N (%)	
DH/TH	8/33 (24)
Non-DH/TH	25/33 (76)
Prior LOT, n (%)	
1	50 (79)
2	10 (16)
3	3 (5)
Prior CAR T cell therapy, n (%)	5 (8)
Primary refractory, n (%)	37 (59)
Best response to 1L treatment, n/n (%)	
CR	10/37 (27)
PR	17/37 (46)
SD	3/37 (8)
PD	7/37 (19)
Receiving 2L treatment and were refractory to or progressed < 12 months of 1L treatment,[d] n (%)	36 (57)

[a]Arm 4, n = 29; Arm 10, n = 34; demographics and baseline characteristics for Arm 4 and Arm 10 previously published separately.[10,11] [b]*MYC* and *BCL2* and/or *BCL6* translocations. [c]DH/TH data per central lab not available for 30 (48%) patients. [d]Patients with 2L disease and early relapse.

- Per eligibility criteria, all patients were eligible for HDT-ASCT upon enrollment
- 57% of patients receiving 2L treatment were refractory to or relapsed < 12 months of 1L treatment

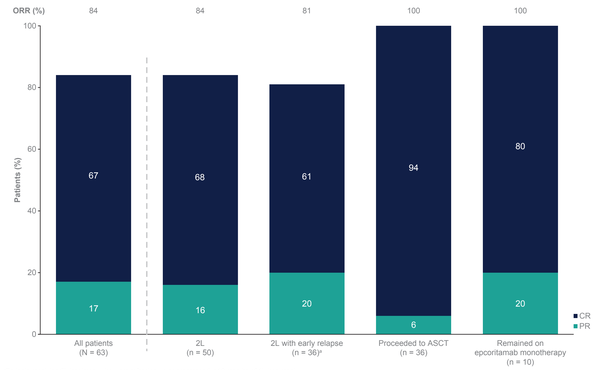
Patient Disposition and Treatment Exposure



Regimen	Treatment	Proceeded to ASCT		Remained on epcoritamab		Did not proceed to ASCT or remain on epcoritamab	
		n	Median cycles initiated (range)	n	Median cycles initiated (range)	n	Median cycles initiated (range)
Epcoritamab + R-DHAX/C	Epcoritamab	16	4 (3–7)	5	24 (10–41)	8	3 (1–4)
	R-DHAX/C	16	3 (2–3)	5	3 (1–3)	8	2.5 (1–3)
Epcoritamab + R-ICE	Epcoritamab	20	4 (2–6)	5	13 (11–21)	9	5 (2–10)
	R-ICE	20	3 (2–3)	5	3 (2–3)	9	3 (2–3)

- Median follow-up was 18.3 months (95% CI, 13.8–38.8)
- Median relative CIT dose intensity was ≥ 80%; CIT dose intensity was not impacted by concomitant use of epcoritamab

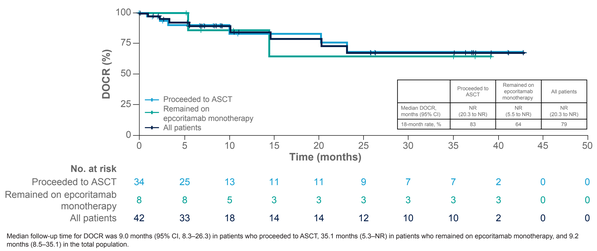
High Response Rates Were Observed Across Subgroups



[a]Patients receiving 2L treatment who were refractory to or progressed < 12 months of 1L treatment.

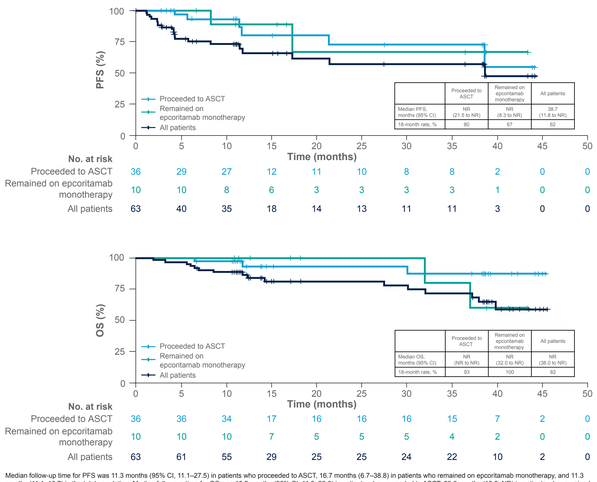
- 6 patients converted from SD or PR to CR while on epcoritamab monotherapy (range, cycles 4–7)

Durable Complete Responses Were Achieved



Median follow-up time for DOCR was 9.0 months (95% CI, 8.3–26.3) in patients who proceeded to ASCT, 35.1 months (5.3–NR) in patients who remained on epcoritamab monotherapy, and 9.2 months (8.5–35.1) in the total population.

PFS and OS Were Sustained



Median follow-up time for PFS was 11.3 months (95% CI, 11.1–27.5) in patients who proceeded to ASCT, 16.7 months (6.7–38.8) in patients who remained on epcoritamab monotherapy, and 11.3 months (11.1–16.7) in the total population. Median follow-up time for OS was 15.2 months (95% CI, 11.8–38.8) in patients who proceeded to ASCT, 28.6 months (10.9–NR) in patients who remained on epcoritamab monotherapy, and 18.3 months (13.8–38.8) in the total population.

Prolonged Survival in 2L Setting, Including Patients With Early Relapse

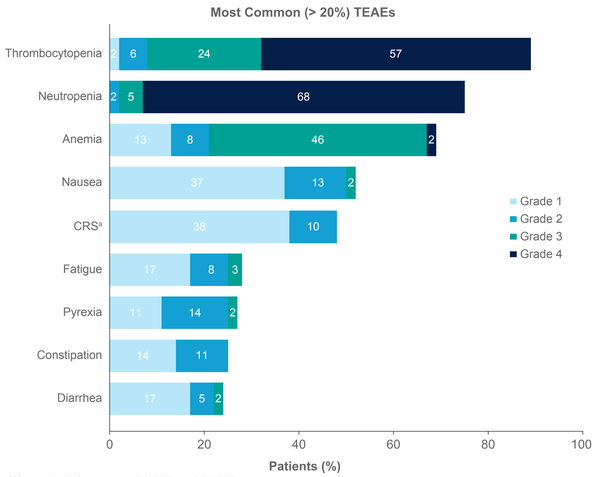
	2L (n = 50)	2L with early relapse[a] (n = 36)	2L with late relapse[b] (n = 14)
DOCR			
18-month rate, %	80	81	81
Median, months (95% CI)	NR (20.3–NR)	NR (10.1–NR)	NR (5.5–NR)
PFS			
18-month rate, %	62	58	75
Median, months (95% CI)	38.7 (11.5–NR)	38.7 (11.5–NR)	21.5 (4.4–NR)
OS			
18-month rate, %	82	77	100
Median, months (95% CI)	NR (32.0–NR)	NR (30.1–NR)	NR (32.0–NR)

[a]Patients receiving 2L treatment who were refractory to or progressed < 12 months of 1L treatment. [b]Patients receiving 2L treatment who were refractory to or progressed ≥ 12 months of 1L treatment.

Consistent Safety Profile

	Epcoritamab + CIT (N = 63)
TEAEs, n (%)	63 (100)
Grade ≥ 3 TEAEs	61 (97)
Serious TEAEs	34 (54)
TEAEs leading to treatment discontinuation, n (%)[a]	7 (11)
Fatal TEAEs, n (%)	0

[a]TEAEs leading to treatment discontinuation were thrombocytopenia (n = 2), anemia, febrile neutropenia, Guillain–Barré syndrome, ICANS, lower respiratory tract infection, myocardial infarction, neurotoxicity, neutropenia, neutrophil count decreased, oral herpes, platelet count decreased, pneumonia, and streptococcal endocarditis (n = 1 each). Patients could have multiple TEAEs leading to treatment discontinuation.



[a]CRS occurred in 48% of patients (grade 1, 24/30 [80%]; grade 2, 6/30 [20%]).

- ICANS occurred in 3% of patients (grades 1 and 2, n = 1 each)
- 16% of patients had febrile neutropenia (grade 3, 9 [14%]; grade 4, 1 [2%])
- 17% of patients had serious infections