ABCL - 615

EPCORE NHL-6: Phase 2 Study of Subcutaneous Epcoritamab as Outpatient Treatment for 2L+ Relapsed/Refractory Diffuse Large B-cell Lymphoma

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Objective

- To assess long-term efficacy and safety of patients with relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL) treated with epcoritamab and monitored in the outpatient setting in the United States and Puerto Rico

Conclusion

- Responses observed with epcoritamab were durable, and the median overall survival was 27.2 months
- Higher complete response rates (57%) observed in the 2L group suggested enhanced benefit with using epcoritamab in earlier lines of therapy
- Overall response rate was 64% and the complete response rate was 49% in patients with ≥ 1 prior lines of therapy
- The overall safety profile remained consistent with previous reports with no new safety signals identified with longer follow-up
- The results support feasibility of outpatient administration and monitoring of epcoritamab in 2L+ DLBCL without mandatory hospitalization

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Introduction

- Epcoritamab, a CD3×CD20 bispecific antibody approved for relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL) after ≥2 prior lines of therapy, is administered subcutaneously with inpatient monitoring for 24 hours after the first full dose required in the initial United States Prescribing Information or European Summary of Product Characteristics[1,2]
- Outpatient administration may overcome barriers associated with inpatient monitoring, making treatment with epcoritamab more accessible to patients in community-based clinics while reducing treatment costs
- Previous reports from the EPCORE NHL-6 study (NCT05451810) demonstrated feasibility of outpatient monitoring after the first full dose of epcoritamab in patients with 2L+ DLBCL[3,4]
  - Most patients (92%) received the first full dose of epcoritamab in the outpatient setting, with only 13.6% of these being admitted for the management of cytokine release syndrome during the first full dosing period
- Based on the EPCORE NHL-6 study, the U.S. Prescribing Information was updated to remove mandatory inpatient monitoring following the first full dose for patients with DLBCL or high-grade B-Cell lymphoma with assessment by treating physician, whether hospitalization or outpatient monitoring is appropriate
- Here we present the efficacy and safety from the EPCORE NHL-6 trial with a longer median follow-up of 17.3 months

Methods

Figure 1: EPCORE NHL-6 (NCT05451810) Study Design

R/R DLBCL key inclusion criteria:
- Adults ≥18 years
- R/R DLBCL[a,b]
  - –DLBCL, NOS (de novo or transformed from FL or MZL)
  - –HGBCL double-hit or triple-hit lymphoma DLBCL (with *MYC* and *BCL-2* and/or *BCL-6* translocations)
  - –FLBL
- R/R disease and ≥1 prior line of therapy, including ≥1 anti-CD20 monoclonal antibody-containing therapy
- Failed prior ASCT or ineligible for ASCT

Data cutoff: November 11, 2025
Median follow-up: 17.3 months

Epcoritamab: Dose escalation and dose expansion (28-day cycle)

Agent	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10+
Epcoritamab	Step-up dosing (SUD): D1: SUD1 (0.16 mg) D8: SUD2 (0.8 mg) D15, D22: full dose (48 mg)	QW full dose (48 mg)	Q2W full dose (48 mg)							Q4W full dose (48 mg)

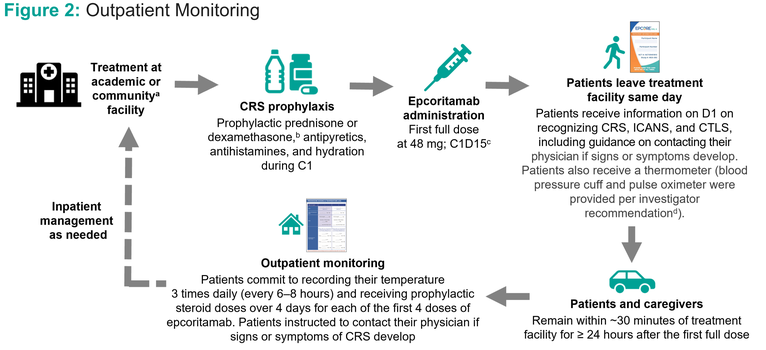
Mandatory CRS prophylaxis
- Administered during C1
- Dexamethasone (preferred) 15 mg IV or oral, or equivalent corticosteroid, administered on D1–4, D8–11, D15–18, and D22–25
- Other premedications included diphenhydramine and acetaminophen, administered prior to each epcoritamab dose on D1, D8, D15, and D22 of C1
- Administer 2–3 L of oral fluids during the 24 hours prior to epcoritamab, 500 mL isotonic IV fluids immediately before treatment, and 2–3 L of oral fluids during the 24 hour after treatment; hold antihypertensive medications for 24 hours prior to each epcoritamab treatment

Primary endpoints
- Percentage of patients who experienced grade ≥3 events of
  - CRS
  - ICANS
  - Neurotoxicity

Key secondary endpoints
- Investigator-assessed ORR and CRR
- TEAEs

[a]According to the 5th edition of WHO classification of hematolymphoid tumors. [b]Based on most recent representative pathology report.
ASCT, autologous stem cell transplantation; C, cycle; CRR, complete response rate; CRS, cytokine release syndrome; D, day; DLBCL, diffuse large B-cell lymphoma; FL, follicular lymphoma; FLBL, follicular large B-cell lymphoma; HGBCL, high-grade B-cell lymphoma; IV, intravenous; MZL, marginal zone lymphoma; NOS, not otherwise specified; ORR, overall response rate; QW, once weekly; R/R, relapsed/refractory; SUD, step-up dosing; TEAE, treatment-emergent adverse event; WHO, World Heath Organization.

Figure 2: Outpatient Monitoring



[a]A center not affiliated with teaching/academic institutions. [b]Most patients received dexamethasone as preferred prophylaxis for CRS. [c]All patients in this presentation received the first full dose of epcoritamab on C1D15. [d]Thermometers were provided for mandatory temperature checks, and blood pressure cuff and pulse oximeter were provided for optional blood pressure and oxygen saturation checks in C1.
C, cycle; CRS, cytokine release syndrome; CTLS, clinical tumor lysis syndrome; D, day; ICANS, immune effector cell–associated neurotoxicity syndrome.

Results

Table 1: Treatment Exposure and Disposition

	Overall (N=92)
Median study follow-up (95% CI), months	17.3 (15.4, 18.9)
Epcoritamab exposure	
Duration, median (range), day	158.5 (8–1025)
Number of cycles, median (range), n	6 (1–35)
Ongoing epcoritamab treatment, n (%)	27 (29.3)
Discontinued epcoritamab treatment, n (%)	65 (70.7)
AE	20 (21.7)
Disease progression	36 (39.1)
Symptomatic deterioration	1 (1.1)
Withdrawal by patient	5 (5.4)
COVID-19 infection	1 (1.1)
Other	2 (2.2)

AE, adverse event; CI, confidence interval.

Table 2: Baseline Characteristics

Characteristic	2L Patients (n=42)	3L+ Patients (n=50)	Overall (N=92)
Median age, years (range)	74.0 (37–87)	64.5 (28–86)	69.0 (28–87)
<65	11 (26.2)	25 (50.0)	36 (39.1)
65 to <75	11 (26.2)	14 (28.0)	25 (27.2)
≥75	20 (47.6)	11 (22.0)	31 (33.7)
Female, n (%)	15 (35.7)	24 (48.0)	39 (42.4)
Ann Arbor stage, n (%)			
I	5 (11.9)	3 (6.0)	8 (8.7)
II	4 (9.5)	4 (8.0)	8 (8.7)
III	8 (19.0)	11 (22.0)	19 (20.7)
IV	25 (59.5)	32 (64.0)	57 (62.0)
DLBCL type, n (%)			
De novo	38 (90.5)	35 (70.0)	73 (79.3)
Transformed	4 (9.5)	15 (30.0)	19 (20.7)
Patients with chromosomal alteration per local laboratory, n (%)			
Double-hit lymphoma	7 (16.7)	9 (18.0)	16 (17.4)
Triple-hit lymphoma	2 (4.8)	2 (4.0)	4 (4.3)
ECOG performance status, n (%)			
0	17 (40.5)	19 (38.0)	36 (39.1)
1	21 (50.0)	28 (56.0)	49 (53.3)
2	4 (9.5)	3 (6.0)	7 (7.6)
IPI, n (%)			
0–2	22 (52.4)	23 (46.0)	45 (48.9)
≥3	20 (47.6)	27 (54.0)	47 (51.1)
Bulky disease by investigator at baseline, n (%)			
<7 cm	33 (78.6)	37 (74.0)	70 (76.1)
7–10 cm	6 (14.3)	6 (12.0)	12 (13.0)
>10 cm	3 (7.1)	7 (14.0)	10 (10.9)

2L, second line; 3L+, third line and beyond; DLBCL, diffuse large B-cell lymphoma; ECOG, Eastern Cooperative Oncology Group; IPI, international prognostic index.

Table 3: Treatment History and Prior Systemic Therapies

Characteristic	2L Patients (n=42)	3L+ Patients (n=50)	Overall (N=92)
Number of prior lines of anticancer therapy, median (range)	1 (1–1)	3 (2–7)	2 (1–7)
Prior lines of anticancer therapy, n (%)			
1	42 (100.0)	0	42 (45.7)
2	0	19 (38.0)	19 (20.7)
3	0	17 (34.0)	17 (18.5)
≥4	0	14 (28.0)	14 (15.2)
Time from last prior anticancer therapy to first epcoritamab dose, median (range), months	6.6 (1–207)	4.1 (0–79)	4.3 (0–207)
Prior CAR T therapy, n (%)	0	22 (44.0)	22 (23.9)
Refractory to prior CAR T therapy	0	15 (30.0)	15 (16.3)
Prior stem cell transplant, ASCT, n (%)	1 (2.4)	6 (12.0)	7 (7.6)
Patients refractory to first line anticancer therapy,[a] n (%)	26 (61.9)	30 (60.0)	56 (60.9)
No response	11 (26.2)	16 (32.0)	27 (29.3)
Relapsed within 6 months after therapy completion	15 (35.7)	14 (28.0)	29 (31.5)

[a]Patients were considered refractory if they did not respond to the prior treatment (stable disease or progressive disease) or initially responded (partial response or above) and progressed during therapy or < 6 months after completion of therapy.
2L, second line; 3L+, third line and beyond; ASCT, autologous stem cell transplant; CAR T, chimeric antigen receptor T-cell.

Table 4: Treatment-Emergent Adverse Events

Patients with ≥1 TEAE, n (%)	Overall (N=92) All Grade	Overall (N=92) Grade 3–4
Any TEAE	92 (100)	75 (81.5)
Most common TEAEs (≥10% patients with grade 3–4 TEAE)		
Anemia	32 (34.8)	15 (16.3)
Neutropenia	15 (16.3)	11 (12.0)
Neutrophil count decreased	15 (16.3)	12 (13.0)
Lymphocyte count decreased	15 (16.3)	10 (10.9)
Hyperglycemia	21 (22.8)	12 (13.0)
TEAEs of special interest, n (%)		
CRS	37 (40.2)	2 (2.2)[a]
CTLS	0	0
ICANS	7 (7.6)	1 (1.1)
Neurological events	57 (62.0)	8 (8.7)
Pyrexia	17 (18.5)	0
Cytopenia	58 (63.0)	47 (51.1)
Injection site reaction	29 (31.5)	0
Serious infection	24 (26.1)	21 (22.8)
COVID-19	19 (20.7)	8 (8.7)
Second primary malignancy	10 (10.9)	4 (4.3)

[a]CRS event was grade 3.
CRS, cytokine release syndrome; CTLS, clinical tumor lysis syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; TEAE, treatment-emergent adverse event.

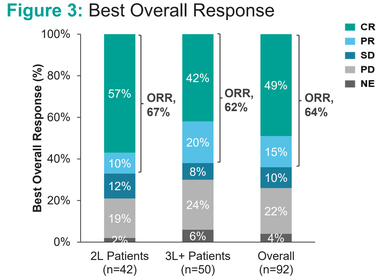
- Grade 5 TEAEs were reported in 16 (17.4%) patients, and none were related to drug:
  - Most frequent (>1 patient) grade 5 TEAEs: malignant neoplasm progression (n=6), COVID-19 (n=3)
- In 21 (22.8%) patients TEAEs led to treatment discontinuation

Table 5: CRS and ICANS Events Were Primarily Low Grade

Patients with ≥1 TEAE, n (%)	2L Patients (n=42)	3L+ Patients (n=50)	Overall (N=92)
CRS	17 (40.5)	20 (40.0)	37 (40.2)
Grade 1	7 (16.7)	13 (26.0)	20 (21.7)
Grade 2	9 (21.4)	6 (12.0)	15 (16.3)
Grade 3	1 (2.4)	1 (2.0)	2 (2.2)
Grade 4–5	0	0	0
ICANS	3 (7.1)	4 (8.0)	7 (7.6)
Grade 1	1 (2.4)	3 (6.0)	4 (4.3)
Grade 2	1 (2.4)	1 (2.0)	2 (2.2)
Grade 3	1 (2.4)	0 (0)	1 (1.1)
Grade 4–5	0	0	0

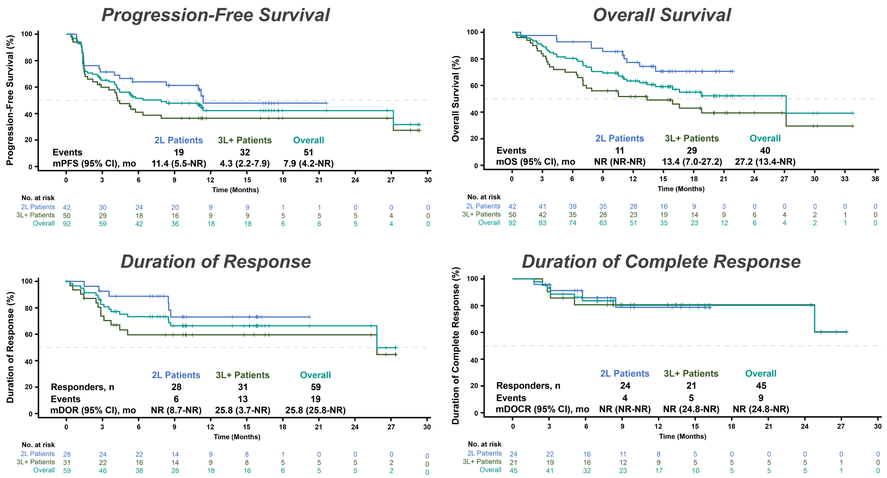
2L, second line; 3L+, third line and beyond; CRS, cytokine release syndrome; ICANS, immune effector cell–associated neurotoxicity syndrome; TEAE, treatment-emergent adverse event.

Figure 3: Best Overall Response



2L, second line; 3L+, third line and beyond; CI, confidence interval; CR, complete response; NE, not evaluable; ORR, overall response rate; PD, progressive disease; PR, partial response; SD, stable disease.

Figure 4: Clinical Outcomes



- Overall estimated 9- and 12-month DOCR (95% CI) was 80.3% (64.0%, 89.7%) and 80.3% (64.0%, 89.7%), respectively
- Overall estimated 12- and 18-month OS (95% CI) was 63.4% (52.6%, 72.5%) and 55.0% (43.2%, 65.3%), respectively

2L, second line; 3L+, third line and beyond; +, censored observation; CI, confidence interval; mDOCR, median duration of complete response; mDOR, median duration of response; mOS, median overall survival; mPFS, median progression-free survival rate; NR, not reached.