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Phase 3 Results From the EPCORE FL-1 Trial of Epcoritamab With Lenalidomide and Rituximab (R^2) Versus R^2 for Relapsed or Refractory Follicular Lymphoma

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Introduction

- Most patients with follicular lymphoma (FL) experience disease relapse and the duration of remission is shorter with each subsequent line of therapy,[1] underscoring the need for more effective therapies in earlier lines
- The combination of lenalidomide plus rituximab (R^2) is a chemotherapy-free standard of care in relapsed/refractory (R/R) FL; however, outcomes remain suboptimal for many patients[2]
- Epcoritamab is a CD3×CD20 bispecific antibody, approved as monotherapy for R/R FL after ≥ 2 prior lines of treatment,[3–5] which when combined with lenalidomide and rituximab may augment antilymphoma activity and lead to improved clinical outcomes in patients with R/R FL[6–8]
  - Unique among CD3×CD20 T-cell engagers, preclinical studies have demonstrated minimal interference between epcoritamab and rituximab antitumor activity when combined[9]
- Early data from the phase 1b/2 EPCORE® NHL-2 trial (NCT04663347) with fixed-duration epcoritamab plus R^2 for R/R FL showed deep and durable responses with encouraging clinical outcomes and manageable safety[10]

Study Design

EPCORE FL-1: Phase 3, Global, Randomized, Open-Label Study

Key eligibility criteria
- Histologically confirmed CD20+ FL
- Grade 1-3a, Stage II-IV
- ≥ 1 prior treatment including anti-CD20 mAb plus an alkylating agent
- Met ≥ 1 GELF criterion

Stratification factors
- Disease status:
  - 2L: > or ≤ 2 years since last therapy
  - 3L+: ≥ or < 6 months since last therapy
- Region: US/EU vs Rest of World

Fixed-Duration: 12 Cycles (28-Day Cycles)

Randomization 1:1

Epcoritamab (48 mg) plus R^2
- **Epcoritamab** (3-SUD cycle 1: QW;[a,b] cycles 2–3, QW; cycles 4–12, Q4W)
- **Rituximab** (375 mg/m^2), 5 cycles (cycle 1, QW; cycles 2–5, Q4W)
- **Lenalidomide** (20 mg), 12 cycles (cycle 1–12, QD, D1–21)

R^2
- **Rituximab** (375 mg/m^2), 5 cycles (cycle 1, QW; cycles 2–5, Q4W)
- **Lenalidomide** (20 mg), 12 cycles (cycle 1–12, QD, D1–21)

- **Dual primary endpoints: ORR per IRC and PFS per IRC**
- Key secondary endpoints: CR rate per IRC, OS, and MRD[c]
- Additional secondary endpoints: DOR, DOCR, TTNLT, safety, and PRO assessments

Data cutoff: May 24, 2025; Median follow-up: 14.8 months[d]
Enrollment period: October 2022 – January 2025

[a]Two step-up dosing (SUD) regimens during cycle 1 to mitigate the risk of cytokine release syndrome: either a 2-SUD (0.16 mg on cycle 1 day 1, 0.8 mg on cycle 1 day 8), or 3-SUD (0.16 mg on cycle 1 day 1, 0.8 mg on cycle 1 day 8, 3 mg on cycle 1 day 15) regimen, followed by full dose 48 mg. The 3-SUD regimen was implemented after reduced CRS severity and incidence had been observed in the EPCORE NHL-1 FL trial (NCT03625037).[11] [b]The 24 mg epcoritamab plus R^2 arm was closed to enrollment based on the superior efficacy for the 48 mg dose from EPCORE NHL-2.[10] Only the data for the optimal dose explored (48 mg) are presented here. [c]Minimal residual disease data are forthcoming in a future analysis. [d]The data presented here are from the second planned interim analysis (May 24, 2025) after 78% Information Fraction for PFS had occurred.

Objective

- We present pivotal efficacy and safety data from the phase 3 EPCORE FL-1 trial (NCT05409066) of epcoritamab+R^2 versus R^2 alone for R/R FL

Results

Table 1: Baseline Demographics and Disease Characteristics Were Generally Balanced

Characteristic	Epcoritamab+R^2 (N = 243)	R^2 (N = 245)	Overall (N = 488)
Median age, years (range)	60 (30, 84)	63 (24, 89)	61 (24, 89)
≥ 65, n (%)	88 (36)	106 (43)	194 (40)
Male, n (%)	139 (57)	138 (56)	277 (57)
Race, n (%)			
Asian	63 (26)	54 (22)	117 (24)
Black	6 (2)	2 (< 1)	8 (2)
White	168 (69)	184 (75)	352 (72)
Ethnicity, n (%)			
Hispanic	29 (12)	28 (11)	57 (12)
ECOG, n (%)			
0	166 (68)	170 (69)	336 (69)
1–2	77 (32)	75 (31)	152 (31)
Ann Arbor stage, n (%)			
II	37 (15)	44 (18)	81 (17)
III–IV	206 (85)	201 (82)	407 (83)
FLIPI score, n (%)			
0–1	63 (26)	56 (23)	119 (24)
2	79 (33)	76 (31)	155 (32)
3–5	100 (41)	113 (46)	213 (44)
Bulky disease (≥ 7 cm), n (%)	47 (19)	61 (25)	108 (22)

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Table 2: Treatment History Was Generally Balanced Across Epcoritamab+R^2 and R^2

	Epcoritamab+R^2 (N = 243)	R^2 (N = 245)	Overall (N = 488)
Median time from initial diagnosis to randomization, years (range)	4.5 (0.2, 30.3)	5.3 (0.1, 43.0)	5.0 (0.1, 43.0)
Number of prior lines of therapy, median (range)	1 (1, 7)	1 (1, 6)	1 (1, 7)
1, n (%)	145 (60)	141 (58)	286 (59)
2, n (%)	58 (24)	61 (25)	119 (24)
≥ 3, n (%)	40 (16)	43 (18)	83 (17)
Prior anti-CD20 antibody, n (%)	243 (100)	245 (100)	488 (100)
Prior anti-CD20 antibody containing chemotherapy, n (%)	239 (98)	240 (98)	479 (98)
Prior bendamustine in last line, n (%)	53 (22)	47 (19)	100 (20)
Prior R^2, n (%)	8 (3)	9 (4)	17 (3)
POD24,[a] n (%)	106 (44)	93 (38)	199 (41)
Refractory to 1L therapy, n (%)	86 (35)	81 (33)	167 (34)
Refractory to anti-CD20 antibody, n (%)	104 (43)	103 (42)	207 (42)
Refractory to last line of therapy, n (%)	84 (35)	82 (33)	166 (34)
Double refractory[b]	91 (37)	91 (37)	182 (37)

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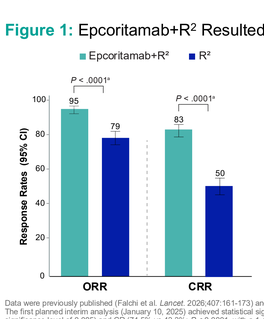
[a]POD24 is defined as progression of disease ≤ 2 years from the date of initiation of frontline therapy. [b]Double refractory is refractory to prior anti-CD20 therapy and prior alkylator therapy.

Figure 1: Epcoritamab+R^2 Resulted in Higher Response Rates Versus R^2

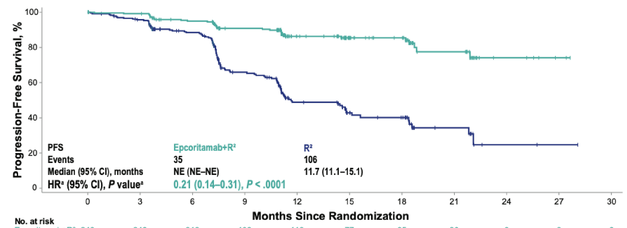


	Epcoritamab+R^2 (N = 243)	R^2 (N = 245)
ORR, n (%)	231 (95)	194 (79)
CRR, n (%)	201 (83)	122 (50)
PR, n (%)	30 (12)	72 (29)
SD, n (%)	1 (< 1)	17 (7)
PD, n (%)	7 (3)	16 (7)
NE,[b] n (%)	4 (2)	18 (7)

Data were previously published (Falchi et al. *Lancet*. 2026;407:161-173) and reproduced with permission under the terms of the CC BY 4.0 license. The first planned interim analysis (January 10, 2025) achieved statistical significance for ORR (N = 232; 95.7% vs 81.0%; $P < 0.0001$, with a 1-sided significance level of 0.005) and CR (74.5% vs 43.3%; $P < 0.0001$, with a 1-sided significance level of 0.025).
[a]Nominal P value by stratified Cochran-Mantel-Haenszel method. [b]Patients with no post-baseline disease assessment were also included.

- DOR and DOCR were improved with epcoritamab+R^2 (Supplemental Materials accessible via the QR code)

Figure 2: Epcoritamab+R^2 Resulted in Superior PFS per IRC With 79% Risk Reduction



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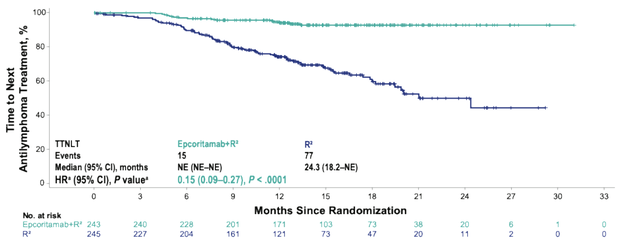
Median follow-up for PFS: epcoritamab+R^2 (14.4m), R^2 (11.5m). The first planned interim analysis (January 10, 2025) achieved statistical significance on PFS, HR 0.21 (95% CI 0.13, 0.33) $P < 0.0001$, with a 1-sided significance level of 0.0023.
[a]Nominal P value is based on stratified log-rank test. Hazard ratio is estimated using stratified Cox proportional hazards model. This analysis was performed on the 78% information fraction.

- Concordance rate was 94% for PFS between IRC and investigator assessment
- The estimated 16-month PFS was 85.5% (95% CI: 79.7, 89.7) for epcoritamab+R^2 and 40.2% (95% CI: 31.8, 48.4) for R^2
- PFS showed trends in favor of epcoritamab+R^2 for all prespecified subgroups (Supplemental Materials)
- OS showed a positive trend with epcoritamab+R^2 (Supplemental Materials)

Figure 3: Epcoritamab+R^2 Extended Time to Next Treatment



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Median follow-up for TTNLT: epcoritamab+R^2 (14.6m), R^2 (14.1m). TTNLT results are for descriptive purposes only.
[a]Nominal P value is based on stratified log-rank test. Hazard ratio is estimated using stratified Cox proportional hazards model.

- At 16 months, 92.8% of patients treated with epcoritamab+R^2 remained free from new antilymphoma treatment compared with 64.9% of patients treated with R^2

Table 3: Manageable AEs With No New Safety Signals

	Epcoritamab+R^2 (N = 243)		R^2 (N = 238)	
Adverse Event, n (%)	**Any Grade**	**Grade ≥ 3**	**Any Grade**	**Grade ≥ 3**
Any adverse event	242 (100)	219 (90)	235 (99)	161 (68)
Serious adverse event	135 (56)	–	69 (29)	–
Adverse event leading to treatment discontinuation	46 (19)	–	29 (12)	–
Epcoritamab	21 (9)	–	–	–
Rituximab	7 (3)	–	12 (5)	–
Lenalidomide	45 (19)	–	29 (12)	–
Adverse event of clinical interest > 20%[a,b]				
Infections[c]	188 (77)	81 (33)	125 (53)	37 (16)
Neutropenia	180 (74)	167 (69)	123 (52)	100 (42)
Cytokine release syndrome	85 (35)	–	1 (< 1)	–
Anemia	68 (28)	19 (8)	41 (17)	11 (5)
Thrombocytopenia	67 (28)	23 (9)	44 (18)	15 (6)
Pyrexia	58 (24)	1 (< 1)	33 (14)	3 (1)
Rash	58 (24)	19 (8)	53 (22)	9 (4)
COVID-19	54 (22)	7 (3)	32 (13)	4 (2)

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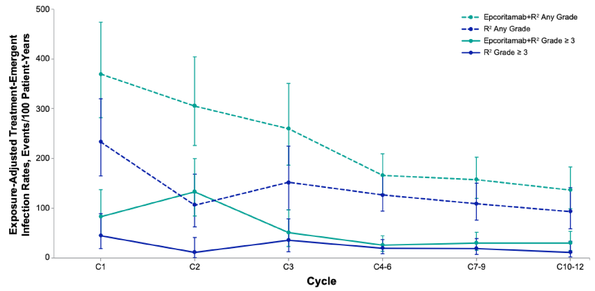
[a]Neutropenia, anemia, pyrexia, rash and COVID-19 are grouped terms comprising multiple clinically related Preferred Terms. [b]This includes the AESI of CRS.
[c]Events were in the MedDRA system organ class "Infections and Infestations." No grade 5 infections were reported.

- Neutropenia was manageable and few patients discontinued any study drug (epcoritamab+R^2, 3%; R^2, 2%)
  - Incidence of febrile neutropenia: epcoritamab+R^2, 6%; R^2, 3%
- Fatal adverse events were rare (epcoritamab+R^2, 2%; R^2, 4%)
- Despite higher rates of AEs in the epcoritamab+R^2 arm, most patients completed the prescribed regimen (median relative dose intensity ≥ 90% for epcoritamab+R^2)

Figure 4: Infection Risk Peaked in Cycles 1 and 2, Decreased Thereafter, and Stabilized After Cycle 4



EAIR (per 100 PY) = patients with ≥ 1 infection event ÷ patient-years at risk × 100, calculated separately by infection category and cycle group. Risk time was censored at the earliest of first qualifying infection event, death, end of the TEAE observation window, or last known alive date/data cutoff.

- Grade ≥ 3 exposure-adjusted treatment-emergent infection rates with epcoritamab+R^2 declined after cycle 2 and remained stable from cycle 4 onward, approaching rates observed with R^2 alone
- Infections were manageable and few patients discontinued any study drug (epcoritamab+R^2, 6%; R^2, 1%)

Table 4: CRS Was Low Grade With Epcoritamab+R^2

	Epcoritamab+R^2 2-SUD N = 110	Epcoritamab+R^2 3-SUD[a] N = 133
CRS, n (%)	50 (45)	35 (26)
CRS grade, n (%)		
1	40 (36)	28 (21)
2	10 (9)	7 (5)
CRS signs and symptoms, n (%)*		
Fever	49 (98)	33 (94)
Hypotension	9 (18)	6 (17)
Hypoxia	1 (2)	2 (6)
Time to first CRS onset from first full dose, days, median (range)	1 (< 1, 6)	1.5 (< 1, 10)
Time to CRS resolution, days, median (range)	1 (< 1, 12)	1 (< 1, 26)
CRS interventions, n (%)[a]		
Treated with tocilizumab	12 (24)	9 (26)
Treated with corticosteroid	23 (46)	13 (37)

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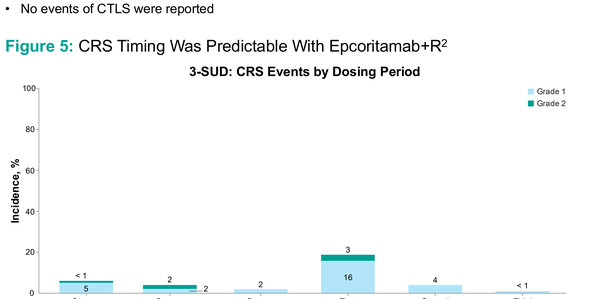
*Of patients who had CRS.

- Hydration and dexamethasone were utilized for CRS prophylaxis
- One event of ICANS was observed and was grade 1
- No discontinuations due to CRS and ICANS. All events resolved
- No events of CTLS were reported

Figure 5: CRS Timing Was Predictable With Epcoritamab+R^2



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[a]The 3-SUD regimen was implemented based off the EPCORE NHL-1 FL trial (NCT03625037).[11]

Conclusion

- In this phase 3 trial in patients with 2L+ FL, fixed-duration epcoritamab plus R^2 was superior to R^2
  - 79% reduction in the risk of disease progression or death
  - Higher rates and durable deep responses (CRR: 83% for epcoritamab+R^2, 50% for R^2; DOCR: not reached for epcoritamab+R^2, 18.6 months for R^2)
  - Benefit was consistent across broad patient subgroups, including both low- and high-risk populations
  - Superior TTNLT and positive trend in OS for epcoritamab+R^2
- The safety profile was manageable in the outpatient setting and remained consistent with the known toxicities of the individual components
- Grade ≥ 3 infection risk peaked in cycles 1 and 2 and stabilized from cycle 4 onward
- Epcoritamab+R^2 is a novel chemotherapy-free, fixed-duration therapy suitable for outpatient administration, and this regimen sets a new benchmark as standard of care in 2L+ FL

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Disclosures

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