

Indirect comparison of epcoritamab vs chemoimmunotherapy, mosunetuzumab, or odronextamab in follicular lymphoma

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Key Points

- In this indirect comparison, epcoritamab significantly improved response and survival vs CIT in patients with relapsed or refractory third-line or higher FL.
- Epcoritamab also showed clinically relevant, numerically higher ORRs and improved safety vs mosunetuzumab or odronextamab.

This matching-adjusted indirect comparison evaluated the efficacy of epcoritamab vs standard of care (SOC), mosunetuzumab, or odronextamab, and assessed safety vs mosunetuzumab and odronextamab. Individual patient-level data from the EPCORE NHL-1 follicular lymphoma (FL) cohort for epcoritamab were used with pooled data from SCHOLAR-5 for SOC (mostly chemoimmunotherapy [CIT]), and aggregate data from GO29781 for mosunetuzumab and ELM-2 for odronextamab. Trial populations were match-adjusted using propensity score weights for key baseline characteristics. Compared with SOC/CIT, epcoritamab provided significantly higher response rates (overall response rate [ORR], 90.9% vs 56.8%; $P < .001$; complete response [CR] rate, 73.7% vs 32.0%; $P < .001$). Epcoritamab showed numerically higher ORR (90.9% vs 80.0%; $P = .067$) and CR rate (72.8% vs 60.0%; $P = .159$) vs mosunetuzumab. Epcoritamab provided significantly higher ORR (91.5% vs 80.5%; $P = .026$) and numerically lower CR rate (67.5% vs 73.4%; $P = .428$) vs odronextamab. Epcoritamab did not have any grade ≥ 3 cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS; any grade) events compared with CRS (grade ≥ 3) in 2.2% and 3.9% and ICANS in 4.4% and 0.8% of patients treated with mosunetuzumab and odronextamab, respectively ($P < .001$). In addition to being a convenient subcutaneous option, epcoritamab showed significantly superior response rates and survival outcomes vs SOC/CIT among patients with relapsed or refractory FL after ≥ 2 systemic therapies. Epcoritamab also exhibited clinically relevant, numerically higher ORRs and demonstrated improved safety for CRS (grade ≥ 3) and ICANS vs mosunetuzumab or odronextamab. These trials were registered at www.ClinicalTrials.gov as #NCT03625037, #NCT02500407, and #NCT03888105.

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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 are provided via publicly accessible study registries/databases as required by law. For more information, please contact ClinicalTrials@genmab.com.

The full-text version of this article contains a data supplement.

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Introduction

Follicular lymphoma (FL) is the most common indolent lymphoma and the second most common subtype of B-cell lymphoma, representing an estimated 20% to 25% of all cases.¹⁻³ FL is generally considered incurable with current therapies.⁴ First-line (1L) therapy typically involves chemoimmunotherapy (CIT), with the most common CIT regimen being bendamustine-rituximab.^{5,6} According to findings from the StiL and BRIGHT studies, rituximab with cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP) may be favored when there is a concern for occult transformation or to mitigate the risk of immune suppression linked with bendamustine.¹ The GALLIUM trial, however, demonstrated superior progression-free survival (PFS) and delayed time to next treatment with obinutuzumab in combination with CIT, including CHOP, compared with rituximab-based treatment in 1L FL.^{7,8} The RELEVANCE study highlighted that rituximab plus lenalidomide (R²) showed comparable efficacy as a frontline treatment compared with standard rituximab plus CIT.^{9,10}

Although most patients with FL respond to initial therapy, an estimated 20% of patients with FL treated with frontline therapies are refractory to or relapse within 2 years of treatment, and the disease becomes increasingly resistant to treatment with each successive line of therapy (LOT).⁴ The most common regimens in patients who receive second-line (2L) therapy include rituximab monotherapy, bendamustine-rituximab, and R-CVP (rituximab-cyclophosphamide/vincristine/prednisone).⁶ The SCHOLAR-5 study, a retrospective cohort study of treatment patterns and outcomes for patients with relapsed or refractory (R/R) FL receiving standard-of-care (SOC) treatment in real-world clinical settings after ≥ 3 systemic therapies, found that CIT was the most frequently used regimen among patients receiving 2L therapy.¹¹ The AUGMENT trial highlighted that R² led to a significant improvement in PFS compared with rituximab alone and is considered a preferred 2L treatment.¹² Patients with progression of disease within 24 months after 1L therapy (POD24) who respond to 2L treatment may be candidates for high-dose chemotherapy followed by autologous stem cell transplant (ASCT).¹³

Several novel therapies have demonstrated improved response rates and survival benefits in R/R FL.¹⁴ Three chimeric antigen receptor T-cell (CAR T) therapies, axicabtagene ciloleucel, tisagenlecleucel, and lisocabtagene maraleucel, are approved by the US Food and Drug Administration (FDA) for FL after ≥ 2 systemic therapies.^{14,15} However, CAR T therapy is associated with substantial challenges, such as complex referral processes, manufacturing wait times and failures, caregiver burden, concerns regarding treatment toxicity, nonrelapse mortality rates as high as 16.2%,¹⁶ and burdensome out-of-pocket costs for patients.^{16,17} Recently, the off-the-shelf CD3 \times CD20 T-cell-engaging bispecific antibodies (bsAbs) epcoritamab, mosunetuzumab, and odronextamab have demonstrated therapeutic benefit in patients with R/R FL after ≥ 2 systemic therapies, with epcoritamab and mosunetuzumab currently approved by the FDA for this indication.¹⁸⁻²⁰

Epcoritamab is a novel, subcutaneous CD3 \times C20 bsAb currently approved for the treatment of adults with R/R large B-cell lymphoma and FL, after ≥ 2 systemic therapies.¹⁹ Additionally, the

FDA has granted “breakthrough therapy designation” to epcoritamab for the treatment of patients with R/R FL in this setting.²¹ In the FL cohort of the EPCORE NHL-1 trial (ClinicalTrials.gov identifier: NCT03625037), epcoritamab showed clinically meaningful activity and manageable safety in patients with R/R grade 1 to 3A FL.²² After a median follow-up of 17.4 months, patients with R/R FL showed high overall response rates (ORRs; 82.0%) and complete response (CR) rates (62.5%).²² Other CD3 \times CD20 bsAbs with demonstrated efficacy and safety in R/R FL after ≥ 2 systemic therapies include IV mosunetuzumab (ORR of 80.0% and CR rate of 60.0%, with a median follow-up of 37.4 months, based on GO29781) and IV odronextamab (ORR of 80.5% and CR rate of 73.4%, with a median follow-up of 20.1 months, based on ELM-2).²³⁻²⁶

In the absence of head-to-head data, we conducted an unanchored matching-adjusted indirect comparison (MAIC) to compare the efficacy of epcoritamab vs SOC/CIT and mosunetuzumab or odronextamab in patients with R/R FL after ≥ 2 systemic therapies. We also assessed the safety (cytokine release syndrome [CRS] and immune effector cell-associated neurotoxicity syndrome [ICANS] events) with epcoritamab vs mosunetuzumab and odronextamab. In addition, rates of neutropenia (grade ≥ 3) and infection (grade ≥ 3) were reported descriptively.

Methods

Study population and data sources

Epcoritamab vs SOC/CIT. Outcomes in SCHOLAR-5 were reported by mutually exclusive LOTs (third line [3L], fourth line, and fifth line or higher); therefore, data were pooled to generate outcomes for ≥ 3 L. Baseline characteristics and outcomes for a pooled cohort of patients initiating ≥ 3 LOTs in SCHOLAR-5 (from 2014 to 2020) were generated using a weighted average of the reported sample size for each LOT. A MAIC analysis was conducted by adjusting for imbalances in the key baseline characteristics between individual patient-level data for 128 patients with FL grade 1 to 3A from EPCORE NHL-1 (ClinicalTrials.gov identifier: NCT03625037) and published SCHOLAR-5 data for 128 patients who could have contributed >1 LOT, resulting in a pooled sample of 206 LOTs. Match adjustments for imbalances were made in the following baseline characteristics: age ≥ 65 years, sex, Eastern Cooperative Oncology Group (ECOG) performance status, disease stages III/IV, Follicular Lymphoma International Prognostic Index (FLIPI) score of ≥ 3 , bulky disease, prior ASCT, prior CAR T therapy, POD24, refractory to last LOT, and proportion with ≥ 3 prior LOTs.

Epcoritamab vs mosunetuzumab. The efficacy comparisons between epcoritamab and mosunetuzumab used individual patient-level data from the FL 1 to 3A cohort of EPCORE NHL-1 (data cutoff: April 2023; median follow-up, 17.4 months) and aggregate patient data from GO29781 (ClinicalTrials.gov identifier: NCT02500407; data cutoff: May 2023; median follow-up, 37.4 months).^{22,23} Given the differences in the inclusion/exclusion criteria of the EPCORE NHL-1 and GO29781 trials, comparisons between epcoritamab and mosunetuzumab used patients from a subgroup of EPCORE NHL-1 that were similar to patients from GO29781 based on its inclusion/exclusion criteria.

The epcoritamab and mosunetuzumab treatment cohorts were match-adjusted for imbalances in the following baseline characteristics: age ≥ 60 years, sex, ECOG performance status, disease stage III/IV, FLIPI score of 3 to 5, bulky disease, prior CAR T therapy, prior ASCT, prior exposure to R² therapy, POD24, refractory to any prior anti-CD20 therapy, double-refractory disease (ie, refractory to anti-CD20 and alkylating therapy), refractory to last prior therapy, and number of prior LOTs (2, 3, or >3).

Safety comparisons used individual patient-level data from the EPCORE NHL-1 FL optimization cohort with 3-step-up dosing, dexamethasone, and hydration (data cutoff: January 2024; median follow-up, 5.7 months).²⁷

Epcoritamab vs odronextamab. The efficacy comparisons between epcoritamab and odronextamab used individual patient-level data from the FL 1 to 3A cohort of EPCORE NHL-1 and aggregate patient data from ELM-2 (ClinicalTrials.gov identifier: NCT03888105; data cutoff: October 2023; median follow-up, 20.1 months).^{23,28} Given the differences in the inclusion/exclusion criteria of the EPCORE NHL-1 and ELM-2 trials, comparisons between epcoritamab and odronextamab used patients from a subgroup of EPCORE NHL-1 that were similar to patients from ELM-2 based on its inclusion/exclusion criteria.

The epcoritamab and odronextamab cohorts were match-adjusted for imbalances in the following baseline characteristics: age ≥ 65 years, age ≥ 75 years, sex, ECOG performance status, disease stages III/IV, FLIPI score of 3 to 5, bulky disease, prior ASCT, prior R² therapy, POD24, double-refractory disease, refractoriness to any prior anti-CD20 therapy, refractoriness to last prior LOT, and proportion with ≥ 3 prior LOTs.

Safety comparisons used individual patient-level data from the EPCORE NHL-1 FL optimization cohort with 3-step-up dosing, dexamethasone, and hydration (data cutoff: January 2024; median follow-up, 5.7 months).

Outcome measures

The efficacy outcomes included ORR, CR rates, PFS, and overall survival (OS). In SCHOLAR-5, response outcomes were determined using either Lugano 2014 criteria or computed tomography scans using the revised International Working Group classification.¹¹ Response assessments in EPCORE NHL-1 and ELM-2 were based on Lugano 2014 criteria, whereas in GO29781, response assessments were based on Cheson 2007 criteria, both of which are based on positron emission tomography.^{23,24,29,30} Safety outcomes for the comparisons vs mosunetuzumab and odronextamab included incidence of CRS (grade ≥ 3) and ICANS (all grades). Deaths directly attributed to COVID-19 were censored at the time of death in the survival analysis to account for the disproportionate impact of the COVID-19 pandemic on trials and outcomes. Where trials reported being affected by the COVID-19 pandemic because of factors such as the timing of trial enrollment and conduct, or regional enrollment patterns, the impact of COVID-19 was adjusted for in the survival analyses. COVID-19 adjustment was applied to the comparison vs SOC/CIT based on SCHOLAR-5, because its study period occurred before the pandemic. COVID-19 adjustment was also performed for the comparative analyses with mosunetuzumab based on the

timing of trial, differential regional enrollment, and the minor impact of COVID-19 reported in Budde et al.²⁵ No adjustments were necessary for comparisons with odronextamab, because ELM-2 was conducted contemporaneously with EPCORE NHL-1.

Statistical analysis

Propensity score weights were used to match-adjust and create balanced cohorts based on key baseline characteristics. Outcomes in the match-adjusted and balanced cohorts were estimated with weighted logistic regression estimating odds ratios (ORs) and 95% confidence intervals (CIs) for responses and adverse events (AEs). Weighted Cox proportional-hazards models were used to estimate hazard ratios (HRs) and 95% CIs for survival.

Results

Epcoritamab vs SOC/CIT

Before match adjustment, there were substantial differences between patient populations. Compared with patients treated with SOC/CIT in SCHOLAR-5, before match adjustment, more patients in the EPCORE NHL-1 cohort (N = 128) had an ECOG performance status of 0 (54.7% vs 36.6%), FLIPI score of ≥ 3 (60.9% vs 35.4%), POD24 (52.3% vs 26.8%), prior CAR T therapy (4.7% vs 0.0%), and ≥ 3 prior LOTs (63.3% vs 57.6%). After match adjustment, the cohorts were balanced on key baseline characteristics (Table 1).

Compared with SOC/CIT, patients treated with epcoritamab had a significantly higher ORR after match adjustment (90.9% vs 56.8%; OR, 7.583; 95% CI, 3.341-17.212; $P < .001$) (Figure 1A). In addition, CR rates with epcoritamab were significantly higher than for SOC/CIT (73.7% vs 32.0%; OR, 5.951; 95% CI, 3.069-11.542; $P < .001$) after match adjustment, demonstrating that the likelihood of achieving a CR with epcoritamab was ~6 times greater than with SOC/CIT (Figure 1A). Patients treated with epcoritamab had significantly improved PFS (HR, 0.321; 95% CI, 0.186-0.556; $P < .001$) and OS (HR, 0.313; 95% CI, 0.157-0.627; $P = .001$) vs SOC/CIT, indicating that treatment with epcoritamab provided a 68% reduction in the risk of progression and 69% reduction in the risk of mortality vs treatment with SOC/CIT (Figure 2).

Epcoritamab vs mosunetuzumab

The EPCORE NHL-1 inclusion criteria were broader than the GO29781 trial inclusion criteria and included more pretreated and harder-to-treat patients, which may be more reflective of patients treated in routine clinical practice. An estimated 37% (47 of 128) of the epcoritamab trial population would have been excluded from GO29781 based on the eligibility criteria of the latter, including ECOG performance status score of 2, baseline hemoglobin of <10 g/dL, impaired renal function (defined as creatinine clearance of ≤ 60 mL/min; EPCORE NHL-1 included patients with creatinine clearance of 45-60 mL/min), and active bronchospasm or chronic obstructive pulmonary disease. As a result, 81 patients in the EPCORE NHL-1 cohort were match-adjusted to the GO29781 cohort for the comparison vs mosunetuzumab (Table 2; supplemental Figure 1).

Table 1. Baseline characteristics of patients in epcoritamab vs SOC/CIT cohorts

Characteristic	Unadjusted epcoritamab FL, % (n = 128)	Adjusted epcoritamab FL, % (ESS = 44)	Pooled SCHOLAR-5, % (n = 206)
Age ≥65 years	52.3	53.5	53.5
Male	61.7	58.4	58.4
ECOG PS 0 (vs 1-2)	54.7	36.6	36.6
Disease stage III-IV	85.2	85.4	85.4
FLIPI score of ≥3	60.9	35.4	35.4
Prior CAR T therapy	4.7	0.0	0.0
Prior ASCT	18.8	20.1	20.1
POD24	52.3	26.8	26.8
Refractory to last prior therapy	68.8	46.4	46.4
≥3 prior LOTs (vs <3)	63.3	57.6	57.6
Bulky disease (>7 cm)	11.7	22.1	22.1

ESS, effective sample size; PS, performance status.

Among the patient populations that met the eligibility criteria (n = 81/128 EPCORE NHL-1 patients), before match adjustment, patients treated with epcoritamab were older (age ≥60 years; 56.8% vs 50.0%), a higher proportion had more advanced disease (stage III or IV; 85.2% vs 76.7%), double-refractory disease (70.4% vs 53.3%), and prior R² exposure (18.5% vs 8.9%), whereas a lower proportion had prior ASCT (19.8% vs 31.1%) (Table 2). After match adjustment, the cohorts were balanced on key baseline characteristics. Epcoritamab showed a numerically higher ORR (90.9% vs 80.0%; OR, 2.509; 95% CI, 0.937-6.722; *P* = .067) and CR rate (72.8% vs 60.0%; OR, 1.785; 95% CI, 0.795-4.008; *P* = .159) than mosunetuzumab after match adjustment (Figure 1B). There were no statistically significant differences in PFS (HR, 0.661; 95% CI, 0.331-1.320; *P* = .241) and OS (HR, 0.434; 95% CI, 0.130-1.455; *P* = .176) for epcoritamab vs mosunetuzumab (Figure 3).

A similar approach was applied to the optimization cohort to remove patients who did not meet the GO29781 trial criteria, resulting in a cohort of 67 patients treated with epcoritamab (supplemental Figure 2). After adjusting for imbalances in potential effect modifiers and prognostic factors in the safety comparison, there were no CRS events (grade ≥3) for epcoritamab vs 2.2% for mosunetuzumab (*P* < .001) (Table 3). No ICANS events of any grade were observed in the epcoritamab optimization cohort vs 4.4% with mosunetuzumab (*P* < .001) (Table 3).³¹ The incidence of neutropenia, including decreased neutrophil count (grade ≥3), was 22.4% and 26.7% for epcoritamab and mosunetuzumab, respectively. Infections (grade ≥3) occurred in 16.4% of patients with epcoritamab and 14.4% with mosunetuzumab.

Epcoritamab vs odronextamab

Compared with patients treated with odronextamab (n = 128), before match adjustment, patients treated with epcoritamab (n = 122) were older (age ≥65 years; 53.3% vs 37.2%); a higher proportion had double-refractory disease (68.9% vs 41.4%), ≥3 prior LOTs (61.5% vs 53.9%), and prior R² exposure (19.7% vs 13.3%); and a lower proportion had prior ASCT (19.7% vs 30.5%) (Table 4). After match adjustment, the epcoritamab and

odronextamab cohorts were balanced on key baseline characteristics. Epcoritamab provided significantly higher ORR (91.5% vs 80.5%; OR, 2.607; 95% CI, 1.126-6.041; *P* = .026) and numerically lower CR rates (67.5% vs 73.4%; OR, 0.752; 95% CI, 0.371-1.525; *P* = .428) vs odronextamab after match adjustment (Figure 1C). There were no statistically significant differences in PFS (HR, 1.021; 95% CI, 0.577-1.805; *P* = .944) or OS (HR, 1.086; 95% CI, 0.520-2.270; *P* = .825) for epcoritamab vs odronextamab (Figure 4).

There were no CRS (grade ≥3) events observed for epcoritamab vs 3.9% with odronextamab in the analysis with the epcoritamab optimization and odronextamab cohorts (*P* < .001) and no ICANS events for epcoritamab vs 0.8% for odronextamab (any grade, *P* < .001; Table 3).³² The incidence of neutropenia (grade ≥3) was 17.5% and 32.0% for epcoritamab and odronextamab, respectively. Infections (grade ≥3) occurred in 18.8% of patients with epcoritamab and 42.2% with odronextamab.

Discussion

In this study, an indirect treatment comparison was conducted to evaluate the efficacy of epcoritamab vs SOC/CIT, mosunetuzumab, or odronextamab, as well as to evaluate the safety of epcoritamab vs mosunetuzumab or odronextamab in patients with R/R FL. After adjusting for imbalances between the study populations, significant differences in efficacy or safety outcomes were observed between the groups. Epcoritamab provided significantly better efficacy and survival vs SOC/CIT; clinically relevant and numerically higher ORRs, comparable survival outcomes, and improved safety vs mosunetuzumab; and comparable survival outcomes and improved safety vs odronextamab in patients with R/R FL after ≥2 systemic therapies. Interestingly, we found a 63% overlap between trial populations for epcoritamab and mosunetuzumab; the EPCORE NHL-1 trial included a more difficult-to-treat population, closely resembling the broader population of patients with ≥3L FL commonly managed in routine clinical practice.^{1,29}

Real-world research has demonstrated a high unmet need for novel therapies in treating patients with R/R FL, given the

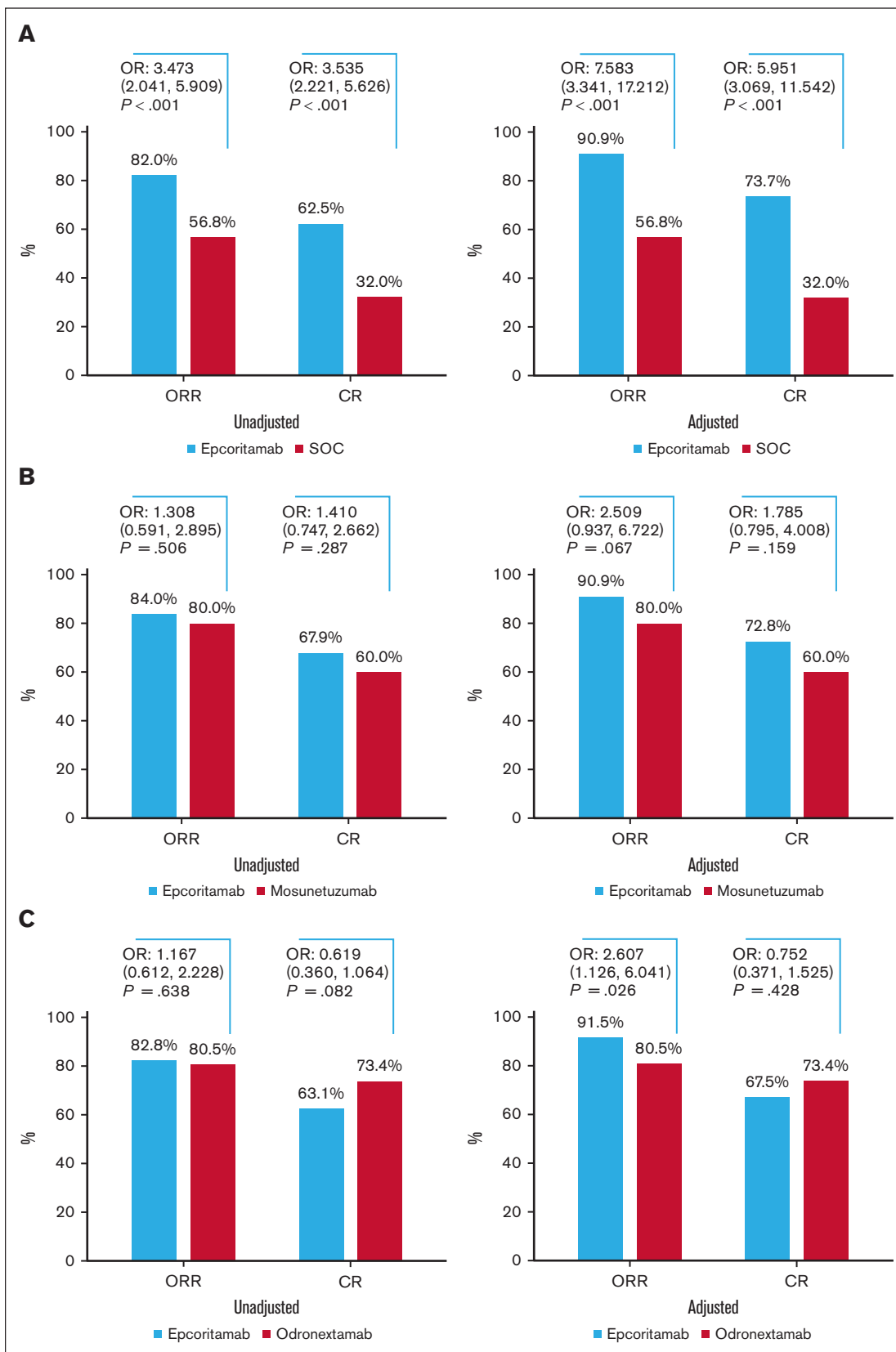


Figure 1. Response outcomes of epcoritamab vs comparators. Unadjusted and adjusted ORR and CR rates with ORs (95% CI) for (A) epcoritamab vs SOC/CIT; (B) epcoritamab vs mosunetuzumab; and (C) epcoritamab vs odronextamab.

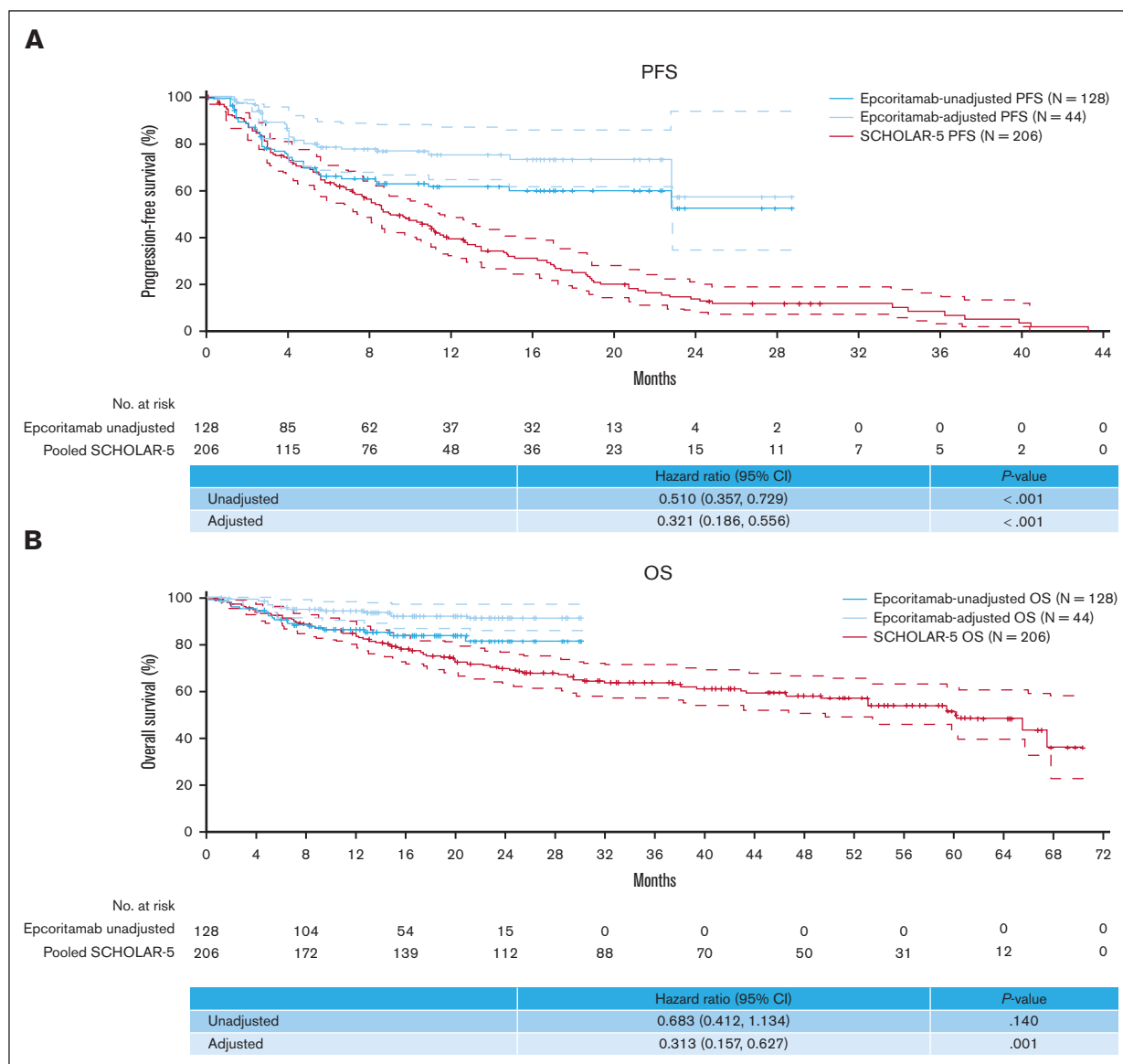


Figure 2. Survival outcomes of epcoritamab vs SOC/CIT. (A) PFS; (B) OS. Comparisons of survival outcomes for epcoritamab vs SOC/CIT were adjusted to account for any reported impact of COVID-19.

widespread use of SOC/CIT regimens across multiple LOTs and particularly for those requiring treatment beyond 2L.^{11,33} Novel therapies, including the bsAbs epcoritamab, mosunetuzumab, and odronextamab, have emerged for the treatment of patients with R/R FL in recent years.^{18,34,35} However, there is limited comparative evidence on the efficacy between these novel therapies vs SOC/CIT and among these novel therapeutic options. In a recent study, an MAIC was used to compare SOC from the Lymphoma Epidemiology of Outcomes Consortium in the United States for Real World Evidence with mosunetuzumab data from the GO29781 trial in patients with R/R FL who had received ≥ 2 prior LOTs. After match adjustment, mosunetuzumab showed clinically relevant and numerically higher ORR and CR rates (ORR, 80%; CR rate, 60%) vs SOC (ORR, 73.0%; CR rate, 52.9%), with mosunetuzumab and SOC having similar PFS.³⁴ To date, there is a

lack of published indirect treatment comparison analyses comparing odronextamab with other treatments.

To our knowledge, this is the first study to compare outcomes not only between a bsAb vs SOC/CIT but also among bsAbs in R/R FL after ≥ 2 systemic therapies. It is possible that differences in response rates between epcoritamab and mosunetuzumab may in part be accounted for by the use of different response criteria used in the studies (Lugano 2014 in EPCORE NHL-1 vs Cheson 2007 in GO29781). Future studies with longer follow-up are needed for continued evaluation of survival benefits among these novel therapies. In terms of safety, epcoritamab was not associated with CRS (grade ≥ 3) unlike both mosunetuzumab and odronextamab. Rates of ICANS were lower with epcoritamab vs the other bsAbs, although ICANS was infrequent with all drugs (0 for epcoritamab,

Table 2. Baseline characteristics used in match adjustment in epcoritamab (expansion and optimization cohorts) vs mosunetuzumab cohort

Characteristic	Efficacy comparison (expansion cohort)		Safety comparison (optimization cohort)		Mosunetuzumab cohort, % (n = 90)
	Unadjusted epcoritamab cohort, % (n = 81)	Adjusted epcoritamab cohort, % (ESS = 37)	Unadjusted epcoritamab cohort, % (n = 67)	Adjusted epcoritamab cohort, % (ESS = 16)	
Age ≥60 years	56.8	50.0	52.2	50.0	50.0
Male	67.9	61.1	58.2	61.1	61.1
ECOG PS 0 (vs 1-2)	65.4	58.9	64.2	58.9	58.9
Disease stage III-IV	85.2	76.7	92.5	76.7	76.7
FLIPI score of ≥3	46.9	44.4	46.3	44.4	44.4
Prior CAR T therapy	4.9	3.3	7.5	3.3	3.3
Prior ASCT	19.8	31.1	19.4	31.1	31.1
POD24	53.1	52.2	52.2	52.2	52.2
Refractory to any prior anti-CD20 therapy	80.2	78.9	79.1	78.9	78.9
Refractory to any prior anti-CD20 and alkylator therapy	70.4	53.3	61.2	53.3	53.3
Refractory to last prior therapy	69.1	68.9	58.2	68.9	68.9
Bulky disease (>6 cm)	25.9	34.4	17.9	34.4	34.4
2 prior LOTs	44.4	37.8	53.7	37.8	37.8
3 prior LOTs	32.1	31.1	28.4	31.1	31.1
>3 prior LOTs (vs ≤3)	23.5	31.1	17.9	31.1	31.1
Prior R ²	18.5	8.9	31.3	8.9	8.9

4.4% for mosunetuzumab, and 0.8% for odronextamab). The improvement observed in this study is likely due to the alternative step-up dosing regimen of epcoritamab (discussed later), which may help mitigate the severity of AEs, such as CRS and ICANS, and lead to better safety outcomes.

Recent advancements in the treatment landscape for R/R FL include the development of novel combination therapies. The triple regimen of tafasitamab, lenalidomide, and rituximab has demonstrated a significant improvement in PFS compared with lenalidomide and rituximab alone, as demonstrated in the phase 3 inMIND trial in the R/R FL setting.³⁶ In addition, mosunetuzumab is under clinical investigation in combination with lenalidomide for the treatment of R/R FL, showing promising efficacy and manageable safety profiles in early-phase studies.³⁷ Epcoritamab in combination with lenalidomide plus rituximab has also demonstrated significant improvements in response rates and PFS in R/R FL (arm 2 of EPCORE NHL-2), and this combination also has an ongoing phase 3 randomized controlled trial in this patient population.³⁸

The global COVID-19 pandemic created considerable challenges for patients with hematologic malignancies, including those undergoing treatment for FL.³⁹ Mortality rates increased substantially during the peak years of the pandemic, 2021 and 2022, coinciding with the widespread prevalence of the Omicron variant.⁴⁰ When comparing treatment outcomes from trials conducted during the COVID-19 pandemic or in regions that were disproportionately affected by the pandemic vs trials that were conducted either before the pandemic or in regions in which the impact was much different, it is important to take the pandemic's impact on trial outcomes into consideration and adjust for this where possible. Such impact can also vary depending on the time

of trial enrollment and conduct vis-à-vis the various waves of the pandemic, the geographic region for trial enrollment (as different trials enrolled from countries that may have been differentially affected by the pandemic), and potential disproportionate representation of risk factors for poor COVID-19 outcomes in the respective trial populations. In our study, it was critical to adjust for the impact of COVID-19 in the comparisons with mosunetuzumab because the GO29781 trial reported minimal impact of the COVID-19 pandemic²⁵; trial enrollment appears to have excluded some heavily affected countries, such as France, and most of the safety data were collected before the highly infectious and impactful waves of the COVID-19 pandemic, such as the Omicron variant. Similarly, the comparison with SCHOLAR-5 warranted adjustment because the data were collected before the COVID-19 pandemic.¹¹

The most common AE associated with bsAbs is CRS, characterized by symptoms such as fever, dyspnea, and hypotension. Prophylactic strategies, such as step-up dosing and steroid administration, may be used to reduce the risk of CRS during bsAb treatment.⁴¹ In EPCORE NHL-1, the incidence of grade ≥3 CRS was 2% in the expansion cohort and 0% in the optimization cohort, whereas the incidence of ICANS (any grade) was 6% in the expansion cohort and 0% in the optimization cohort.²² Notably, the median time to resolution of CRS of any grade remained consistent at 2 days for both cohorts.²² Additionally, the percent of patients requiring tocilizumab for CRS management was lower in the optimization cohort (12%) compared with the expansion cohort (24%).²² An additional step-up dose of 3 mg as well as dexamethasone and adequate hydration were used to mitigate CRS in the optimization cohort. These strategies were associated

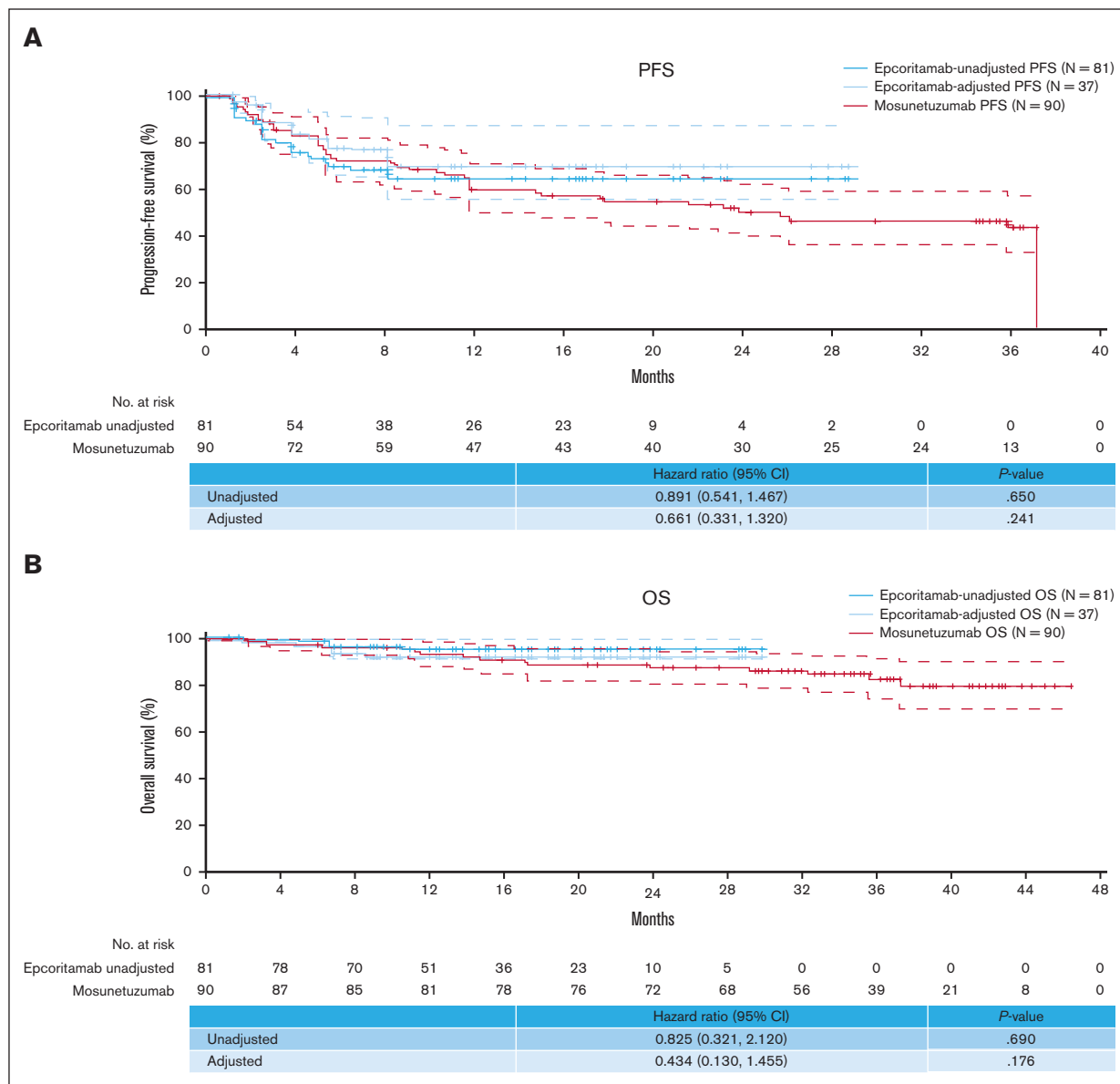


Figure 3. Survival outcomes of epcoritamab vs mosunetuzumab. (A) PFS; (B) OS. Comparisons of survival outcomes for epcoritamab vs mosunetuzumab were adjusted to account for any reported impact of COVID-19.

with a substantial reduction in both the frequency and severity of CRS in the EPCORE NHL-1 optimization cohort as compared with the pivotal expansion cohort.⁴² Indeed, corticosteroid premedication and multiple step-up doses are recommended for the use of bsAbs in this patient population; such strategies were also used

in the trials of mosunetuzumab and odronextamab used for the safety comparisons in this study.^{25,32}

Our findings indicated that there were no CRS (grade ≥ 3) events, which typically require hospitalization in the intensive care unit,⁴³

Table 3. Matching-adjusted safety comparisons for epcoritamab vs mosunetuzumab and odronextamab

AE	Epcoritamab vs mosunetuzumab	Epcoritamab vs odronextamab
CRS (grade ≥ 3)	0.0% vs 2.2%	0.0% vs 3.9%
OR for CRS (95% CI)	0.000 (0.000-0.000); $P < .001$	0.000 (0.000-0.000); $P < .001$
ICANS	0.0% vs 4.4%	0.0% vs 0.8%
OR for ICANS (95% CI)	0.000 (0.000-0.000); $P < .001$	0.000 (0.000-0.000); $P < .001$

Table 4. Baseline characteristics of patients used in match adjustment in epcoritamab (expansion and optimization cohorts) vs odronextamab cohort

Characteristic	Efficacy comparison (expansion cohort)		Safety comparison (optimization cohort)		Odronextamab cohort, % (n = 128)
	Unadjusted epcoritamab cohort, % (n = 122)	Adjusted epcoritamab cohort, % (ESS = 40)	Unadjusted epcoritamab cohort, % (n = 80)	Adjusted epcoritamab cohort, % (ESS = 30)	
Age ≥65 years	53.3	37.2	41.3	37.2	37.2
Age ≥75 years	13.1	9.4	12.5	9.4	9.4
Male	61.5	53.1	56.3	53.1	53.1
ECOG PS of 0 (vs 1-2)	54.9	50.8	62.5	50.8	50.8
Disease stage III-IV	84.4	85.2	91.3	85.2	85.2
FLIPI score of ≥3	60.7	57.8	51.3	57.8	57.8
Prior ASCT	19.7	30.5	23.8	30.5	30.5
POD24	50.8	49.2	50.0	49.2	49.2
Refractory to any prior anti-CD20	77.9	74.2	76.3	74.2	74.2
Refractory to any prior anti-CD20 and alkylator therapy	68.9	41.4	61.3	41.4	41.4
Refractory to last prior therapy	68.9	71.9	58.8	71.9	71.9
Bulky disease (>7 cm for epcoritamab/unknown for odronextamab)	12.3	14.1	12.5	14.1	14.1
≥3 prior LOTs	61.5	53.9	43.8	53.9	53.9
Prior R ²	19.7	13.3	27.5	13.3	13.3

or any instances of ICANS in the epcoritamab cohort compared with the mosunetuzumab and odronextamab cohorts, which could be attributed to the optimized step-up dosing regimen of epcoritamab. This study reported rates of neutropenia (grade ≥3) and infections (grade ≥3), but direct comparisons were limited by the shorter follow-up period: neutropenia occurred in 22.4% of patients with epcoritamab and 26.7% with mosunetuzumab, and 17.5% of patients with epcoritamab and 32.0% with odronextamab, whereas infections were observed in 16.4% of patients with epcoritamab and 14.4% with mosunetuzumab, and 18.8% of patients with epcoritamab and 42.2% with odronextamab. With additional and more comparable follow-up, other elements of safety, such as neutropenia and infections, would be a worthwhile exploration in these comparisons, particularly considering the differing methods of safety data collection in fixed treatment duration vs treat to progression.

Indirect treatment comparisons are subject to methodological limitations, which also apply to our study. First, the process may not fully address issues of bias with respect to the comparability of the trial cohorts and representativeness of the target population. This analysis used available data without an a priori formal power calculation, with a limitation on the effective sample size potentially affecting the precision and reliability of survival estimates. Further research with larger sample sizes may provide more rigor in the precision of the estimates. The limited follow-up for AEs in the optimization cohort may limit the assessment of neutropenia and infections, whereas early-onset events, such as CRS and ICANS, are less affected. Whereas this analysis does not comprehensively explore the impact of duration on treatment, the potential merits and demerits of continued suppression of malignant cells with treatment until progression vs fixed treatment duration deserves further explorations with longer follow-up. Although this study does not include comparisons of quality-of-life data, future research can consider assessing how treatments affect patients' health-related

quality of life. Interestingly, data from Jurczak et al suggest that patients with R/R FL treated with epcoritamab reported stable or improved patient-reported outcome scores,⁴⁴ highlighting the potential for this novel agent to maintain quality of life. Examining factors that influence the durability of response would also provide valuable insights to guide treatment decisions and optimize patient outcomes.

Despite these commonly cited limitations, this study has several strengths. Leveraging data from multiple sources, our study provides insights into the treatment effects in the absence of head-to-head trials. To our knowledge, this is the first study to explore treatment comparisons, providing new perspectives into factors that may influence patient outcomes. In addition, this indirect comparison allows for the assessment of treatment outcomes within a single analysis, providing a comprehensive overview of the treatments. The response and survival results of epcoritamab being statistically significantly improved vs SOC/CIT remain robust. Although the SCHOLAR-5 study included patients treated with phosphoinositide 3-kinase inhibitors, which have since been withdrawn from the market, their limited representation in the study suggests that the SCHOLAR-5 outcomes are still relevant to modern clinical practice.^{11,12} Given the available evidence, the described comparative analysis is a transparent and methodologically sound approach to compare epcoritamab with SOC/CIT, mosunetuzumab, and odronextamab in patients with R/R FL after ≥2 systemic therapies.

Conclusions

In this MAIC analysis using individual patient-level data for epcoritamab, pooled data for SOC/CIT, and published aggregate data for mosunetuzumab and odronextamab, results show that in addition to being a convenient subcutaneous option, treatment with epcoritamab demonstrated significantly higher response rates and improved survival compared with SOC/CIT among patients

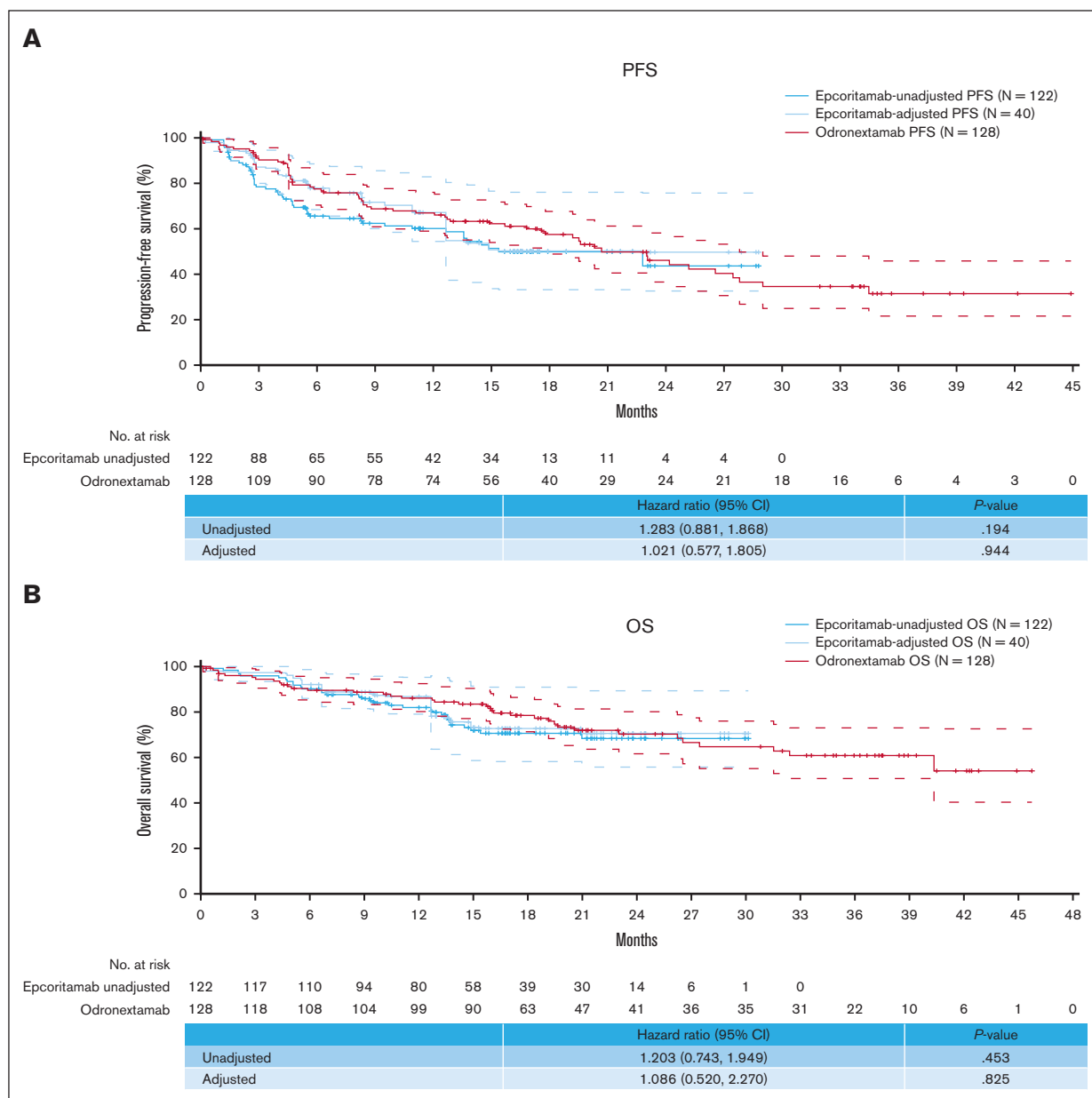


Figure 4. Survival outcomes of epcoritamab vs odronextamab. (A) PFS; (B) OS.

with R/R FL after ≥ 2 systemic therapies. Epcoritamab also showed clinically relevant, numerically higher ORRs and provided comparable survival benefits with improved safety for CRS (grade ≥ 3) and ICANS compared with mosunetuzumab or odronextamab in this patient population. Although findings are subject to limitations of analyses conducted outside of a head-to-head randomized clinical trial, the results underscore the therapeutic benefits of subcutaneous epcoritamab over SOC/CIT and demonstrate a favorable comparison vs mosunetuzumab or odronextamab.

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Authorship

Contribution: A.V.D., S.K.T., K.L., V.C., A.M., Z.D., and A.S. were study investigators; V.C. collected and assembled data; K.C. analyzed data; and all authors contributed to study design, data interpretation, manuscript preparation, review, and revision, and provided final approval of the manuscript.

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