

P1118 LONGER FOLLOW-UP FROM THE PIVOTAL EPCORE NHL-1 TRIAL REAFFIRMS SUBCUTANEOUS EPCORITAMAB INDUCES DEEP, DURABLE COMPLETE REMISSIONS IN PATIENTS WITH RELAPSED/REFRACTORY LARGE B-CELL LYMPHOMA

Topic: 19. Aggressive Non-Hodgkin Lymphoma - Clinical

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Background:

Outcomes are poor for patients with relapsed/refractory (R/R) large B-cell lymphoma (LBCL). Effective treatments that drive deep, durable responses and long-term benefit are needed. In the pivotal EPCORE™ NHL-1 trial (NCT03625037), single-agent epcoritamab showed high complete response (CR) and MRD-negativity rates and a manageable safety profile as an off-the-shelf, subcutaneous, CD3xCD20 T-cell-engaging bispecific antibody (Thieblemont et al, *JCO* 2022).

Aims:

To present updated results from the EPCORE NHL-1 LBCL expansion cohort, including longer follow-up, in a challenging-to-treat population.

Methods:

Patients with R/R CD20+ LBCL received subcutaneous epcoritamab (step-up priming and intermediate doses followed by 48-mg full doses) in 28-d cycles: QW, cycles 1–3; Q2W, cycles 4–9; Q4W, cycles ≥10 until PD or unacceptable toxicity. Informed consent was obtained.

Results:

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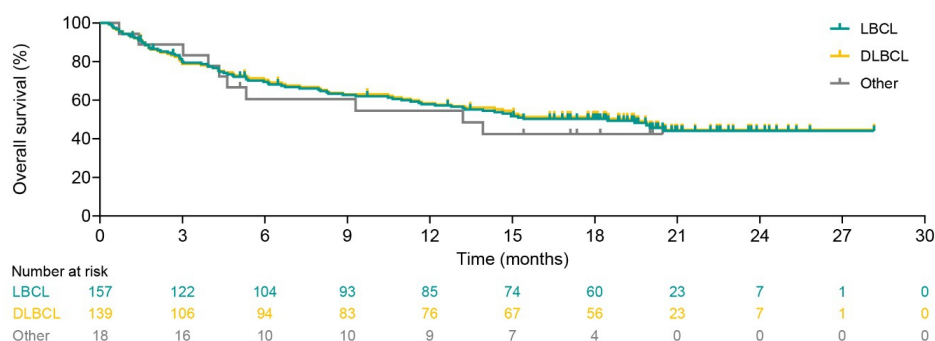
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As of November 18, 2022, of 157 patients (median age, 64 y) with LBCL (including DLBCL [n=139; 12/88 double/triple-hit by FISH], HGBCL [n=9], PMBCL [n=4], and FL grade 3B [n=5]), 36 remain on treatment. Patients had a median of 1.6 y from initial diagnosis to first dose and a median of 3 (range, 2–11) prior lines of treatment; 61% of patients had primary refractory disease, and 39% had prior CAR T, of whom 75% progressed within 6 mo of treatment. Median follow-up was 20 mo (range, 0.3+ to 28.2). Patients received a mean of 9.1 cycles. LBCL overall response and CR rates were 63.1% and 39.5%, respectively, and were consistent for DLBCL (61.9% and 39.6%). Median duration of CR was 20.8 mo. Median time to CR was 2.7 mo; 8 patients converted from partial response to CR at ≥ 36 wk. Median overall survival was 18.5 mo (95% CI, 11.7–not reached [NR]) for patients with LBCL and 19.4 mo (95% CI, 11.7–NR) for patients with DLBCL (**Figure**). Median overall survival was NR (95% CI, NR–NR) in patients who achieved CR; at 9, 12, and 15 mo, an estimated 98.3%, 95.0%, and 88.3% of complete responders were alive, respectively. Additionally, median duration of response among patients with CR was 20.8 mo (95% CI, 17.3–NR), and an estimated 91.2%, 85.2%, and 79.0% of complete responders remained in response at 9, 12, and 15 mo, respectively. Median progression-free survival was NR (95% CI, 18.5–NR) among complete responders; an estimated 91.1%, 87.2%, and 81.3% of complete responders remained progression free at 9, 12, and 15 mo, respectively. The most common treatment-emergent adverse events of any grade (G) were CRS (51%), neutropenia (24%), pyrexia (24%), fatigue (23%), nausea (22%), and diarrhea (21%). Nine patients (6%) had G1–2 ICANS, and 1 patient had a G5 event with confounding factors. Fatal treatment-emergent adverse events occurred in 15 patients; 2 were considered related (COVID-19, ICANS). CRS was predominantly low grade (48% G1–2; 3% G3) and occurred following the first full dose (cycle 1, day 15). One patient discontinued treatment due to G1 CRS.

Summary/Conclusion:

These data with longer follow-up reaffirm single-agent subcutaneous epcoritamab induces durable CRs with improved outcomes and a manageable safety profile for patients with R/R LBCL. No new safety signals were observed in these hard-to-treat patients. These impressive data support the ongoing phase 3 studies evaluating epcoritamab across different lines of treatment and in various combinations.

Figure. Overall survival



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