Subcutaneous epcoritamab (SC epcor) administered outpatient (outpt) for relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL): Results from phase 2 EPCORE NHL-6.

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Background: Epcor is the only SC CD3xCD20 bispecific antibody approved for R/R DLBCL. In initial protocols, hospitalization after the 1st full dose of epcor was required to monitor patients (pts) for and characterize CRS. The EPCORE NHL-6 trial assessed whether R/R DLBCL/FL pts treated with SC epcor across US community and academic sites could be safely monitored in the outpt setting. **Methods:** Eligible pts had R/R DLBCL or FL and at least 2 prior lines of therapy. Epcor was given in 28-d cycles [C]; C1 SUD: 0.16 mg then 0.8 mg, followed by 48 mg; C1–3: QW; C4–9: Q2W; C≥10: Q4W. Pts received safety education, including early identification and reporting of symptoms of CRS and ICANS, and were required to stay ≤30 min of the site of care for 24 h after the 1st full dose. Based on C1 optimization (OPT) findings from EPCORE NHL-1 (Vose ASH 2023, Abs 1729), the trial was amended to implement C1 OPT with hydration and dexamethasone after enrollment of 34 pts. **Results:** At data cutoff, 36 pts (23 DLBCL, 13 FL) received ≥1 dose of epcor (median cycles, 3). 13 and 23 pts were from US academic and community sites, respectively. Median age was 65 y, 67% of pts had extranodal disease, and 39% had prior CAR T. Any grade CRS occurred in 47% of pts and were mostly low grade (G1, n=9; G2, n=7; G3, n=1). Median time to onset of CRS after 1st full dose was 23 h. No CRS events led to discontinuation; 11 pts (31%) were treated with tocilizumab, 8 (22%) with corticosteroids, and 5 (14%) with both. ICANS occurred in 8% (all G1-2) with a median time to onset of 20 days from C1D1, and all resolved. Of 31 pts receiving the 1st full dose, 3 pts (10%) received epcor in the inpatient (inpt) setting while admitted for AEs other than CRS (pain management, leg injury, UTI, n=1 each). The remaining 28 pts (90%) received epcor and were monitored in the outpt setting. 12 total pts had 13 CRS events after the 1st full dose with CRS starting in the outpt setting in 10 pts (G1, n=6; G2, n=4). 7/28 (25%) pts initially monitored as outpts were subsequently managed as inpt for CRS. All 12 pts had resolution of CRS with a median time to resolution of 45 h. **Conclusions:** Pts with R/R DLBCL and FL were successfully treated with SC epcor and monitored in the outpt setting across different types of sites. CRS events occurring in the outpt setting were appropriately managed, and the observed CRS incidence and severity was comparable to that of the pivotal EPCORE NHL-1 trial. These data suggest that SC epcor can be safely administered and pts monitored outpt, and then managed inpt as needed for CRS. Enrollment is ongoing, and a larger dataset with C1 OPT including hydration and dexamethasone, which are anticipated to further lower CRS incidence and severity, will be presented later. Clinical trial information: NCT05451810. Research Sponsor: This study was funded by AbbVie and Genmab A/S.

CRS events by dosing period.

CRS Events N=24	Priming SUD1 n=3	Intermediate SUD2 n=2	1st Full n=13	2nd Full n=4	≥3rd Full n=2
G1	3	2	7	4	0
G2	0	0	6	0	1
G3	0	0	0	0	1

No ≥G4 CRS.