HemaSphere

EHA EUROPEAN HEMATOLOGY ASSOCIATION

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

Wojciech Jurczak*[1], Herve Ghesquieres[2], Yasmin Karimi[3], Chan Cheah[4], Michael Roost Clausen[5], David Cunningham[6], Young Rok Do[7], David Lewis[8], Robin Gasiorowsi[9], Tae Min Kim[10], Marjolein Van Der Poel[11], Michelle Limei Poon[12], Tatyana Feldman[13], Kim Linton[14], Anna Sureda[15], Martin Hutchings[16], Salim Kanoun[17], Laetitia Vercellino[18], Mariana Cota Stirner[19], Stephanie Mcgoldrick[20], Yan Liu[20], Mariana Sacchi[20], Pieternella (Elly) Lugtenburg[21], Catherine Thieblemont[22]

[1]Msc National Research Institute Of Oncology, Kraków, Poland; [2]Hospices Civils De Lyon, Centre Hospitalier Lyon Sud, Pierre-Bénite, France; [3]University Of Michigan Comprehensive Cancer Center,, Ann Arbor, United States; [4]Sir Charles Gairdner Hospital, Nedlands, Australia; [5]Vejle Hospital, Vejle, Denmark; [6]The Royal Marsden Nhs Foundation Trust, Sutton, United Kingdom; [7]Keimyung University Dongsan Medical Center, Daegu, Korea, Rep. Of South; [8]University Hospitals Plymouth Nhs Trust, Derriford Hospital, Plymouth, United Kingdom; [9]Concord Hospital, University Of Sydney, Sydney, Australia; [10]Seoul National University Hospital, Seoul, Korea, Rep. Of South; [11]On Behalf Of The Lunenburg Lymphoma Phase I/Ii Consortium-Hovon/Llpc, Maastricht, Department Of Internal Medicine, Division Of Hematology, Grow School For Oncology And Developmental Biology, Maastricht University Medical Center, Maastricht, Netherlands; [12]National University Hospital, Singapore, Singapore; [13]Hackensack Meridian Health Hackensack University Medical Center, Hackensack, United States; [14]The Christie Nhs Foundation Trust And Manchester Cancer Research Centre, Manchester, United Kingdom; [15]Institut Català D'oncologia, Hospital Duran I Reynals, Idibell, Universitat De Barcelona, L'hospitalet De Llobregat , Barcelona, Spain; [16]Rigshospitalet, Copenhagen University Hospital, , Copenhagen, Denmark; [17]Cancer Research Center Of Toulouse, Toulouse, France; [18]Assistance Publique & Hôpitaux De Paris (Aphp), Hôpital Saint-Louis, Médecine Nucléaire, Université De Paris, Paris, France; [19]Abbvie, North Chicago, United States; [20]Genmab, Princeton, United States; [21]On Behalf Of The Lunenburg Lymphoma Phase I/Ii Consortium-Hovon/Llpc, Erasmus Mc Cancer Institute, University Medical Center, Department Of Hematology, Rotterdam, Netherlands; [22]Assistance Publique & Hôpitaux De Paris (Aphp), Hôpital Saint-Louis, Hémato-Oncologie, Université De Paris, Paris, France

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:

Abstract Book Citations: Authors, Title, HemaSphere, 2023;7(S3):pages. The individual abstract DOIs can be found at https://journals.lww.com/hemasphere/pages/default.aspx.

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