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P1457 DEMOGRAPHICS AND TREATMENT OUTCOMES IN PATIENTS WITH EBV+ PTLD TREATED WITH OFF-THE-SHELF EBV-SPECIFIC CTL (TABELECLEUCEL) UNDER AN ONGOING EXPANDED ACCESS PROGRAM IN EUROPE: FIRST ANALYSES

Topic: 25. Gene therapy, cellular immunotherapy and vaccination - Clinical

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Background: Patients undergoing allogeneic hematopoietic cell transplant (HCT) or solid organ transplant (SOT) are at risk of developing Epstein–Barr virus driven post-transplant lymphoproliferative disorder (EBV$^+$ PTLD), a rare hematologic malignancy, which is often aggressive and life-threatening.

Patients with relapsed or refractory (r/r) EBV$^+$ PTLD have few treatment options with poor outcomes, demonstrating a clear unmet medical need.

Tabelecleucel is an investigational, off-the-shelf, allogeneic EBV-specific T-cell immunotherapy being studied in patients with serious EBV$^+$ diseases (NCT04554914 & NCT03394365) that has demonstrated clinical benefit and favorable safety profile in the treatment of EBV$^+$ PTLD after failure of rituximab (R) ± chemotherapy (Prockop, EBMT 2021, ATC 2021, ASH 2021).

Aims: First analyses of demographics, efficacy and safety results of r/r EBV$^+$ PTLD patients following SOT or HCT who presented between Jul 2020 and Nov 2021 and consented to research.

Methods: Atara Biotherapeutics supports an ongoing expanded access program (EAP) in Europe for patients with EBV$^+$ diseases who have no other treatment options.

Demographics, efficacy and safety data of r/r EBV$^+$ PTLD patients following SOT or HCT who presented to the EAP between Jul 2020 and Nov 2021 and consented to research were analyzed.

Results: A total of 48 EAP requests from 9 countries for patients with EBV$^+$ diseases were received.

Twenty-two patients from 7 countries consented to this research: 16 EBV$^+$ PTLD and 6 EBV$^+$ non-PTLD. Of the 16 PTLD patients 15 received at least one dose of tabelecleucel. Overall, 9 out of 15 (60%) patients achieved a response as assessed by the treating physician, with 6 complete responses and 3 partial responses. Eight out of nine responses were seen after the first cycle.

No adverse events were reported as related to tabelecleucel by the treating physician.

Image:

	EBV⁺ PTLD post HSCT (N=5)	EBV⁺ PTLD post SOT (N=11)	Total (N=16)
Median age (range)	54 (12-64)	48 (12-65)	48.5 (12-65)
Male	3 (60%)	2 (18%)	5 (31%)
ECOG PS ≥ 2 or Lansky PS ≤ 60	1 (20%)	4 (36%)	5 (31%)
Median prior lines of therapy (range)	2 (1-3)	1 (0-4)	1 (0-4)
Treated and response assessed	4 (80%)	11 (100%)	15 (94%)
Responders*/Treated (%)	3/4 (75%)	6/11 (54.5%)	9/15 (60%)
CR*	3 (75%)	3 (28%)	6 (40%)
PR*	-	3 (28%)	3 (20%)

*n (%); * Best overall response*

CR, Complete Response; ECOG, Eastern Cooperative Oncology Group; PR, Partial Response; PS, Performance Score

Summary/Conclusion: The successful execution of this European EAP demonstrates the feasibility to deliver an off-the-shelf allogeneic EBV⁺ T-cell therapy in time-sensitive clinical situations when no other treatment options exist. These data show clinically meaningful outcomes for patients with r/r EBV⁺PTLD post-SOT or post-HCT treated with tabelecleucel consistent with previously reported favorable safety and efficacy profile (Prockop, ASH 2021).