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Real-world Experience with Early Line Ciltacabtagene Autoleucel for Relapsed/Refractory Multiple Myeloma.

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INTRODUCTION

Background:

BCMA-directed chimeric antigen receptor T-cell therapy ciltacabtagene autoleucel (cilta-cel) has demonstrated unprecedented efficacy for patients with relapsed/refractory multiple myeloma (RRMM). It is approved after one prior line of therapy (pLOT) in patients refractory to lenalidomide based on CARTITUDE-4.

Purpose:

We explore the use of early-line (1-3 pLOT) cilta-cel in a real-world setting.

Methods:

We retrospectively analyzed all RRMM patients treated at Moffitt Cancer Center with standard-of-care early-line cilta-cel from 4/2024-8/2025. High-risk cytogenetics were defined as del(17p), t(4;14), t(14;16), and/or 1q21 gain/amplification. Survival was measured by Kaplan-Meier method. Cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) were graded using ASTCT criteria.

RESULTS

A total 45 RRMM patients were included. Median age was 67 (45-79), 31% were female, 71% had high-risk cytogenetics, 9% had extramedullary disease, and median pLOT was 3. Any-grade CRS occurred in 40 patients (89%) (Grade 3 in one patient), and any-grade ICANS occurred in 9 patients (20%). Non-ICANS neurologic events including parkinsonism and cranial nerve palsies occurred in 0 patients and 10 patients (22%) respectively. Infections, all mild to moderate, occurred in 12 patients (27%) of which 11 were viral, 2 were bacterial, and 1 was fungal. One patient required ICU admission for steroid-induced hyperglycemia. There were two deaths, one related to progression of disease and one related to immune effector cell-associated enterocolitis.

Median follow-up was 12 months (3-17 months). The overall response rate was 98% (44/45) with complete response or better rate 76% (34/45). Day-90 clonoSEQ minimal residual disease (MRD) assessment was performed for 35 patients, of which 92% (32/35) were MRD-negative. The 12-month progression-free survival was 85% (95% confidence interval [CI] 68-94) and 12-month overall survival was 95% (CI 81-99).

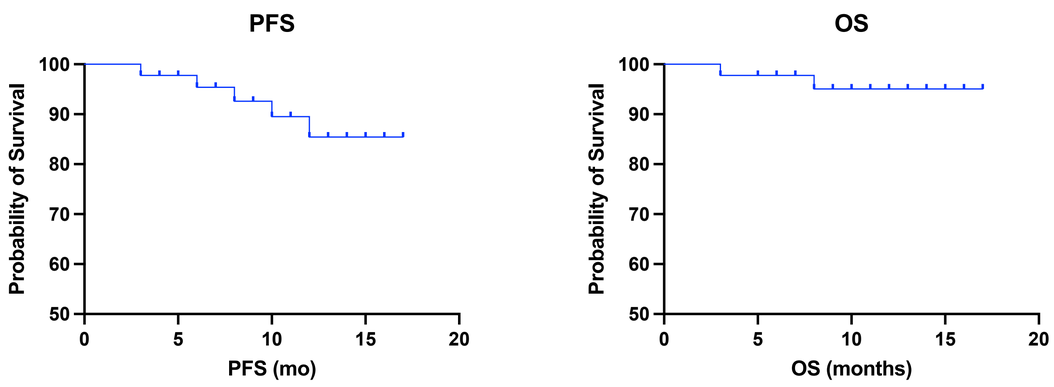

Figure 1. Kaplan-Meier estimates of progression-free survival and overall survival in the Real-World Cohort. PFS, progression-free survival; OS overall survival

Demographics	Real World Cohort *(n=45)*	CARTITUDE-4 *(n=208)*
Age, median (range), yr	67 (45 - 79)	61.5 (27 - 78)
Female, no. (%)	14 (31)	92 (44)
Race/ethnicity		
White, no. (%)	36 (80)	157 (76)
Black, no. (%)	4 (9)	6 (3)
Asian, no. (%)	1 (2)	16 (8)
Missing data or Other, no. (%)	4 (9)	29 (14)
Hispanic ethnic group, no. (%)	2 (4)	18 (9)
High risk cytogenetics, no. (%)	32 (71)	123 (60)
Extramedullary Disease, no. (%)	4 (9)	44 (21)
Bone marrow plasma cells >60% pre-LD, no. (%)	6 (13)	42/206 (20)
ECOG 0-1 at LD, no. (%)	40 (89)	207 (99.5)
Prior lines of therapy		
1, no. (%)	3 (7)	68 (33)
2, no. (%)	16 (36)	83 (40)
3, no. (%)	26 (58)	57 (27)
Triple-class refractory, no. (%)	9 (20)	30 (14)
Penta-class refractory, no. (%)	0 (0)	2 (1)
Bridging therapy, no. (%)	42 (93)	
Bispecific antibody-based bridging therapy, no. (%)	3/42 (7)	
Overall response to bridging therapy (PR or better), no. (%)	12/42 (29)	
Type of response		
CR/sCR, no. (%)	1/42 (2)	
VGPR, no. (%)	1/42 (2)	
PR, no. (%)	10/42 (24)	
SD, no. (%)	13/42 (31)	
PD, no. (%)	9/42 (22)	
Unknown, no. (%)	8/42 (19)	
Clinical Outcomes		
CRS		
All grades, no. (%)	40 (89)	134 (76)
Grade 3-4, no. (%)	1 (2)	2 (1)
ICANS		
All grades, no. (%)	9 (20)	8 (5)
Grade 3-4, no. (%)	0 (0)	0 (0)
Non-ICANS neurologic events		
Parkinsonism, no. (%)	0 (0)	1 (1)
Cranial nerve palsies, no. (%)	10 (22)	16 (9)
Infections		
Viral, no. (%)	11 (24)	
Bacterial, no. (%)	2 (4)	
Fungal, no. (%)	1 (2)	
Best overall response (PR or better), no. (%)	44 (98)	176 (85)
Type of response		
CR/sCR, no. (%)	34 (76)	152 (73)
VGPR, no. (%)	5 (11)	17 (8)
PR, no. (%)	5 (11)	7 (3)
SD, no. (%)	1 (2)	13 (6)
PD, no. (%)	0 (0)	17 (8)
MRD negativity in evaluable patients, no. (%)	32/35 (91)	126/144 (88)
1-year progression-free survival, % (95% CI)	85 (68 - 94)	76 (69 - 81)
Non-relapse mortality, no. (%)	1 (2)	
Cause of death, IEC-EC, no. (%)	1 (2)	
Median follow up, (range), mo	12 (3 -17)	16 (0 - 27)

Table 1. Demographics and clinical outcomes of the Real-World Cohort and the CARTITUDE-4 cilta-cel cohort.

CONCLUSION

Our real-world findings align with the findings in CARTITUDE-4 and support the use of early-line cilta-cel for the treatment of RRMM.

REFERENCES

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