PA-174

eMMpower-CART: Real-World Insights into Early-Line Cilta-cel Outcomes in Multiple Myeloma

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Introduction

- Cilta-cel, a B-cell maturation antigen-targeted chimeric antigen receptor T-cell therapy for relapsed/refractory multiple myeloma (RRMM), has demonstrated sustained efficacy in early lines of therapy in clinical trials[1,2]
- While CARTITUDE trials have demonstrated substantial benefit with cilta-cel in earlier lines of therapy, real-world evidence describing treatment patterns, depth of response, minimal residual disease [MRD] outcomes, and durability of benefit in routine clinical practice remains limited[1,2]
- This study evaluated patient characteristics, treatment patterns, depth of response, MRD negativity, and early survival outcomes among US patients receiving commercial cilta-cel following 1–3 prior lines of therapy

Methods

Study design

- A real-world study using data from the eMMpower multisite retrospective chart review consortium
- The eMMpower consortium is a multisite US real-world evidence collaboration comprising academic and community oncology centers designed to evaluate outcomes among patients with multiple myeloma treated in routine clinical practice

Study population

- Adult patients with RRMM receiving commercial cilta-cel in 2nd to 4th LOT
- Patients with smoldering MM or cilta-cel use in a clinical trial or expanded access program were excluded

Statistical analysis

- Baseline characteristics, bridging therapy patterns, and post-infusion outcomes (MRD status, overall response rate [ORR]) were summarized descriptively
- Overall survival (OS) and progression-free survival (PFS) were evaluated using Kaplan-Meier methods
- Given limited follow-up, multiple parametric survival models were used to assess longer-term OS projections

Key Takeaways

- A single infusion of cilta-cel demonstrated high effectiveness in routine practice among patients treated after 1-3 prior LOTs
- Responses were frequent and deep, with ORR of 98% and nearly three-quarters of patients achieving ≥CR
- MRD negativity was observed in 86% of assessed patients, including majority at the 10^{-6} threshold
- Early PFS and OS outcomes were highly encouraging in a population with significant high-risk disease

Conclusions

- In this real-world cohort of patients receiving commercial cilta-cel after 1–3 prior LOTs, treatment was associated with rapid, deep, and durable responses, including high rates of MRD negativity
- Although follow-up remains limited, exploratory OS extrapolation suggests the potential for durable long term survival with earlier line cilta cel
- Ongoing longitudinal follow-up of patients included in eMMpower will provide additional insights into the durability of response and long-term survival, supporting evaluation of functional cure potential

Results

Patient characteristics

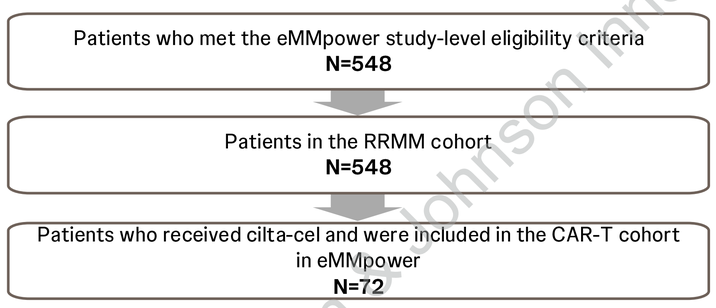
- A total of 72 patients met study criteria (**Figure 1**). Patient demographics and clinical characteristics are summarized in **Table 1**
- Cilta-cel was the most commonly administered in the 3rd (37.5%) or 4th (48.6%) setting, among a clinically high-risk population that includes 61.1% of patients with high-risk cytogenetics

Table 1. Patient characteristics (N=72)

Demographics	
Age, mean (SD) [median], years	66.3 (9.7) [68.0]
Female , n (%)	32 (44.4)
Race, n (%)	
White	56 (77.8%)
Black	8 (11.1%)
Asian	1 (1.4%)
Other/Unknown	7 (9.7%)
Insurance type[a], n (%)	
Medicare	46 (63.9)
Commercial	30 (41.7)
Medicaid	1 (1.4)
Other/Unknown	8 (11.1)
Length of follow-up, mean (SD) [median], months	10.6 (10.1)[6.4]
Clinical characteristics	
R-ISS, n (%)	
Stage I	17 (23.6)
Stage II	27 (37.5)
Stage III	14 (19.4)
Unknown	14 (19.4)
Type of measurable MM disease, n (%)	
No measurable disease - plasma cell only	7 (9.7)
Serum free light chains only	8 (11.1)
Serum measurable (e.g., IgG, IgA, etc.)	54 (75.0)
Unknown	2 (2.8)
Urine measurable only	1 (1.4)
Cytogenetic risk[b], n (%)	
High	44 (61.1)
Standard	19 (26.4)
Unknown	9 (12.5)
Frailty status based on SFS score[c], n (%)	
Nonfrail (score <2)	53 (73.6)
Frail (score ≥2)	17 (23.6)
Unknown	2 (2.8)
ECOG performance status, n (%)	
0	27 (37.5)
1	38 (52.8)
2	5 (6.9)
Unknown	2 (2.8)
Quan-Charlson Comorbidity Index[3]	
Mean (SD) [median]	0.8 (1.25) [0]
Categorical eGFR, n (%)	
Mild to moderate renal impairment (eGFR 30-59)	10 (13.9)
Normal renal function (eGFR ≥60)	62 (86.1)
Cilta-cel line of therapy, n (%)	
2nd line	10 (13.9)
3rd line	27 (37.5)
4th line	35 (48.6)

[a] Patients may be covered by multiple health plans. [b] Defined as 1q+, t(4;14), t(14;16), t(14;20), and/or del(17p) per Tan et al.[4] [c] Evaluated per Facon et al,[5] based on CCI, ECOG, and age categories. ECOG, Eastern Cooperative Oncology Group; eGFR, estimated glomerular filtration rate; IQR, interquartile range; R-ISS, Revised - International Staging System; SD, standard deviation; SFS, Simplified Frailty Scale.

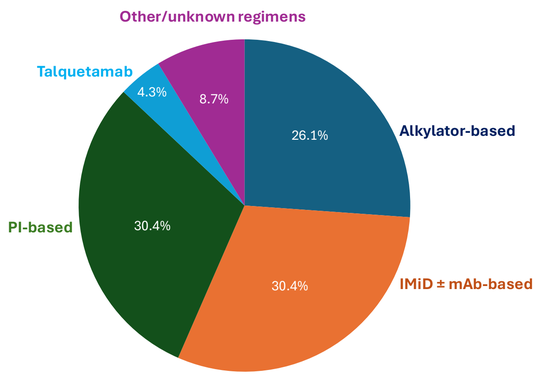
Figure 1. Patient selection



Bridging therapy patterns

- Before cilta-cel infusion, 46 (63.9%) patients received bridging therapy. The median time from bridging therapy initiation to cilta-cel infusion was 1.6 months
- Among bridged patients, 30.4% received immunomodulatory drug ± monoclonal antibody-based regimens, 30.4% proteasome inhibitor-based, 26.1% alkylator-based, 4.3% talquetamab, and 8.7% other/unknown regimens (**Figure 2**)

Figure 2. Distribution of bridging therapies



IMiD, immunomodulatory drug; mAb, monoclonal antibody; PI, proteasome inhibitor.

Post-infusion outcomes

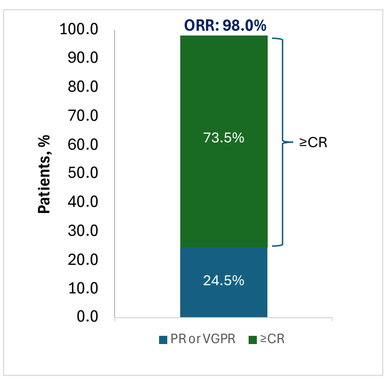
- At a median follow-up of 6.4 months, ORR was 98.0%, including 73.5% ≥complete response (**Figure 3**)
- Among 29 patients with evaluable MRD assessments, 86.2% achieved MRD negativity at 10^{-5} or better, including 64.0% at the 10^{-6} sensitivity threshold (**Table 2**)
- Of 3 patients with serial evaluable MRD assessments, all 3 had sustained MRD negativity (**Figure 4**)

Table 2. Post-infusion MRD negativity

	Study population (N=72)
MRD reported, n (%)	29 (40.3)
MRD status[a]	
MRD negative[b]	25 (86.2)
MRD negativity at the 10^{-5} threshold[b]	9 (31.0)
MRD negativity at the 10^{-6} threshold[b]	16 (55.2)
Time to MRD negativity, mean (SD) [median], days	83.0 (80.4) [64.0]

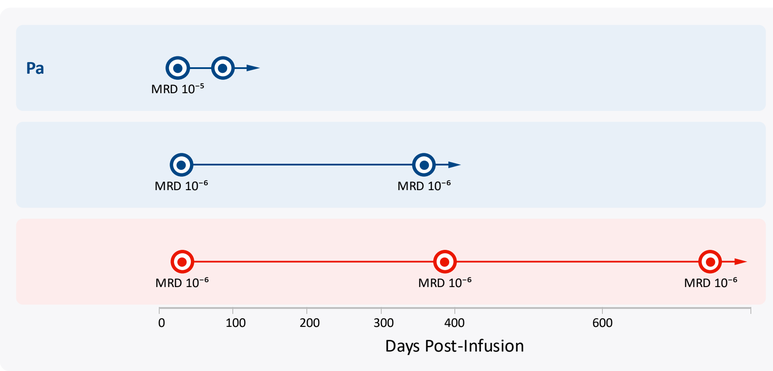
[a] MRD was assessed using multiparameter flow cytometry, next-generation sequencing, or next-generation flow cytometry. [b] Among patients with an evaluable MRD assessment. MRD, minimal residual disease; SD, standard deviation.

Figure 3. ORR



CR, complete response; ORR, overall response rate; PR, partial response; VGPR, very good partial response.

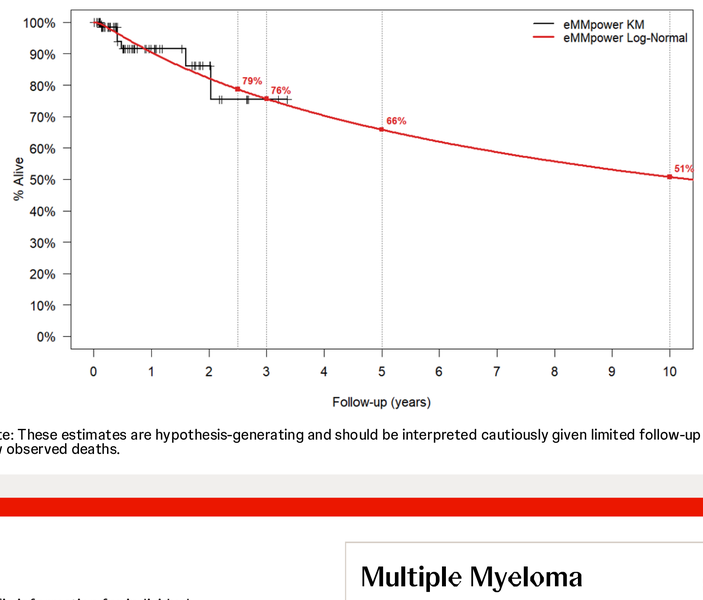
Figure 4. Sustained MRD negativity (10^{-5}–10^{-6})



PFS and OS

- The estimated 6-month and 12-month PFS rates were 98.4% and 92.2% respectively
- In the overall cohort (N=72), OS rates were 93.7% at both 6 and 12 months
- Exploratory OS extrapolation across parametric models projected OS rates of ~79% at 30 months, ~66% at 5 years, and ~51% at 10 years (**Figure 5**)

Figure 5. Long-term OS trend



Note: These estimates are hypothesis-generating and should be interpreted cautiously given limited follow-up and few observed deaths.

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Multiple Myeloma

Disclosures: Binod Dhakal reports serving on advisory boards for BMS, Kite Pharma, Arcellx, Janssen, Sanofi, Pfizer, and Genentech and on speakers' bureaus for BMS, Karyopharm, Janssen, and Sanofi; and research funding from BMS, Janssen, Carsgen, Arcellx, Ichnos, Sanofi, and C4 Therapeutics. Hamza Hashmi reports consulting/speakers' bureau membership for Janssen, Karyopharm, Amgen, and Pfizer. Carlyn R. Tan has received research funding from Janssen, Sanofi, and Takeda; and has served as a consultant for Janssen and Sanofi. Amir Ali has received a consulting fee or honorarium from Takeda and served on a speaker's bureau for Johnson & Johnson. Baylee Bryan has nothing to disclose. Matthew Pianko has received research funding from AbbVie, Ascentage, Bristol Myers Squibb, Janssen, Nektar, Pfizer, Regeneron, and Sanofi; honoraria from Janssen, Karyopharm, Oncopeptides, Pfizer, and Sanofi; and served as a consultant for Janssen and Pfizer. Cindy Varga has received honoraria and research funding from Janssen and research funding; from LavaTherapeutics. Jennifer M. Ahlstrom has served on patient advocacy committees for Janssen, Takeda Oncology, Pfizer, BMS, and Sanofi. Justin Hayne is an employee of Legend Biotech and may own shares/stock options in Legend Biotech. Rafael Fonseca has received consulting fees from AbbVie, Adaptive, Amgen, Apple, BMS/Celgene, GSK, Johnson & Johnson, Karyopharm, Pfizer, RA Capital, Regeneron, and Sanofi; he has served on the Scientific Advisory Board of Caris Life Sciences and the Board of Directors of Antengene, and has a patent for FISH in MM. Saurabh Nagar, Yuehan Zhang, Jinghua He, Sang Kyu Cho, Victoria Alegria, Shuchita Kaila, Zaina Qureshi are employees of Johnson & Johnson and may own shares/stock options in Johnson & Johnson.

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