The 7th World Congress on CONTROVERSIES IN MULTIPLE MYELOMA (COMy)

HEALTH-RELATED QUALITY OF LIFE IN THE CARTITUDE-1 STUDY OF CILTACABTAGENE AUTOLEUCEL (CILTA-CEL) IN PATIENTS WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA (RRMM)

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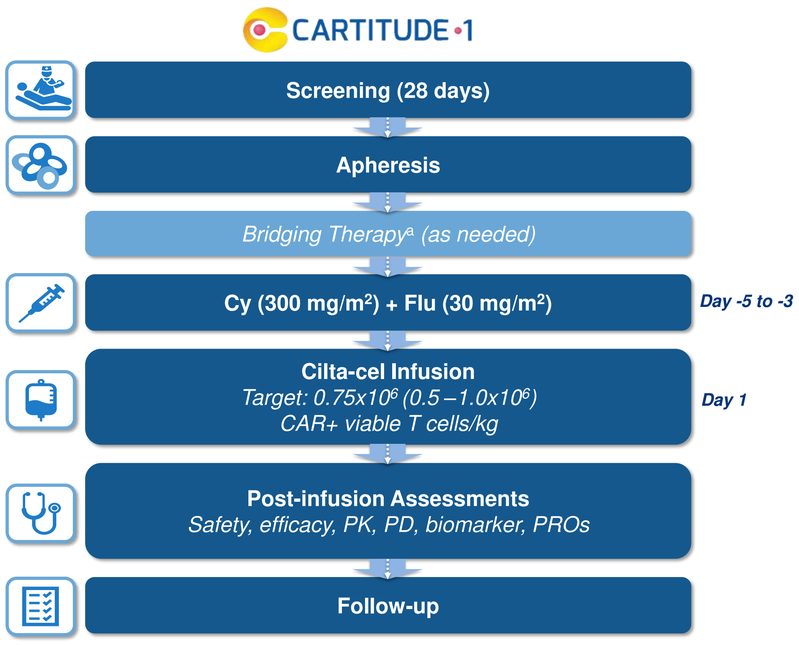
INTRODUCTION

- Multiple myeloma (MM) negatively affects health-related quality of life (HRQoL), and with each relapse, patients with MM experience further declines in HRQoL.[1]
- HRQoL is therefore important to consider in the management of MM and evaluation of new therapies.
- In the phase 1b/2 CARTITUDE-1 study, a single infusion of ciltacabtagene autoleucel (cilta-cel; JNJ-68284528; LCAR-B38M chimeric antigen receptor T cells) yielded deep and durable responses in heavily pretreated (triple-class exposed) patients with RRMM.[2]
  - Overall response rate was 96.9% (95% CI, 91.2–99.4), with 67.0% of patients achieving stringent complete response.
- Here, we present patient-reported outcomes as measured by HRQoL instruments in the phase 2 portion of CARTITUDE-1.

METHODS



Key Eligibility Criteria

- Progressive MM per International Myeloma Working Group criteria, Eastern Cooperative Oncology Group performance status ≤1, measurable disease, ≥3 prior therapies or double refractory, and prior proteasome inhibitor, immunomodulatory drug, anti-CD38 therapy.

PRO Assessments

- Scores transformed to a 0–100 scale
- Higher scores represent
  - Greater HRQoL
  - Better functioning
  - Greater symptom severity
  - Higher level of self-evaluated health status

HRQoL Instrument	Scales Assessed
EORTC QLQ-C30	• GHS, functional scales, symptom scales
EORTC QLQ-MY20 (4 items)	• Emotional health status
EQ-5D-5L VAS	• Current health status (“health today”)

ClinicalTrials.gov number NCT03548207; 01 Sept 2020 data cutoff. [a]Treatment with previously used agent resulting in at least stable disease. CAR, chimeric antigen receptor; Cilta-cel, ciltacabtagene autoleucel; Cy, cyclophosphamide; EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30; EQ-5D-5L, EuroQol 5-dimensional 5-level; Flu, fludarabine; GHS, global health status; HRQoL, health-related quality of life; MM, multiple myeloma; PD, pharmacodynamic; PK, pharmacokinetic; PROs, patient-reported outcomes; QLQ-MY20, Quality of Life Questionnaire myeloma module; VAS, Visual Analogue Scale.

RESULTS

Table 1. Baseline Characteristics

Characteristic	Phase 2 (N=68)
Median age (range), years	62.0 (43–78)
Male, n (%)	43 (63.2)
Prior therapies for MM, median (range)	6 (3–18)
Penta-drug exposed,[a] n (%)	59 (86.8)
Triple-class refractory,[b] n (%)	60 (88.2)
Penta-drug refractory,[a] n (%)	32 (47.1)
EORTC QLQ-C30, mean (SD)	
GHS	62.2 (22.7)
Physical functioning	78.6 (22.5)
Pain	37.0 (31.9)
Fatigue	37.4 (26.1)
EQ-5D-5L VAS, mean (SD)	70.8 (20.6)

01 Sept 2020 data cutoff. [a]≥2 PIs, ≥2 IMiDs, and 1 anti-CD38 antibody; [b]≥1 PI, ≥1 IMiD, and 1 anti-CD38 antibody.
EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30; EQ-5D-5L, EuroQol 5-dimensional 5-level; GHS, health status; IMiD, immunomodulatory drug; MM, multiple myeloma; PI, proteasome inhibitor; QLQ-MY20, Quality of Life Questionnaire Myeloma Module; SD, standard deviation; VAS, Visual Analogue Scale.

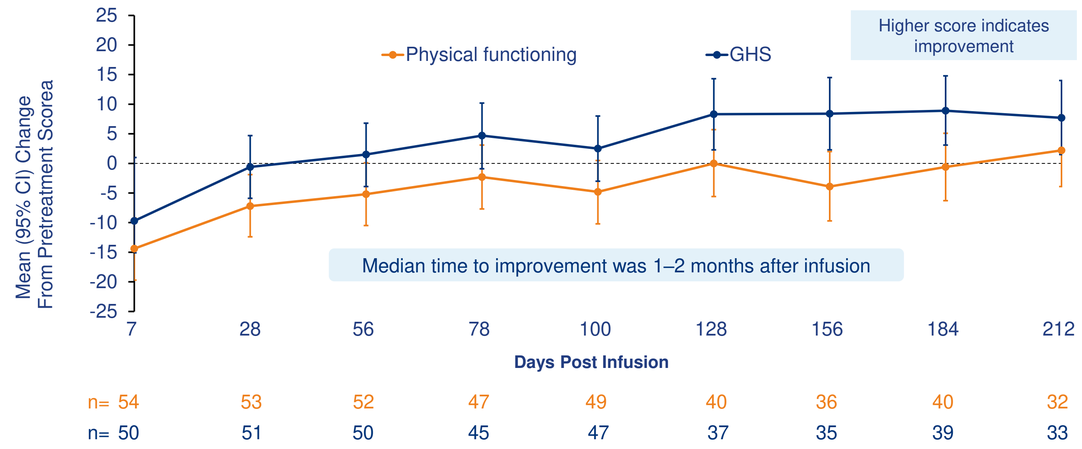
Table 2. Questionnaire Completion Rates

	Questionnaire Completion Rates					
	EORTC QLQ-C30		EORTC QLQ-MY20 (4 items)		EQ-5D-5L VAS	
Days	Expected n	Received n (%)	Expected n	Received n (%)	Expected n	Received n (%)
Baseline	68	63 (92.6)	68	63 (92.6)	68	63 (92.6)
Day 100	65	54 (83.1)	65	53 (81.5)	65	54 (83.1)
Day 212	53	36 (67.9)	53	36 (67.9)	53	36 (67.9)

01 Sept 2020 data cutoff. EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30; EQ-5D-5L, EuroQol 5-dimensional 5-level; QLQ-MY20, Quality of Life Questionnaire Myeloma Module; VAS, Visual Analogue Scale.

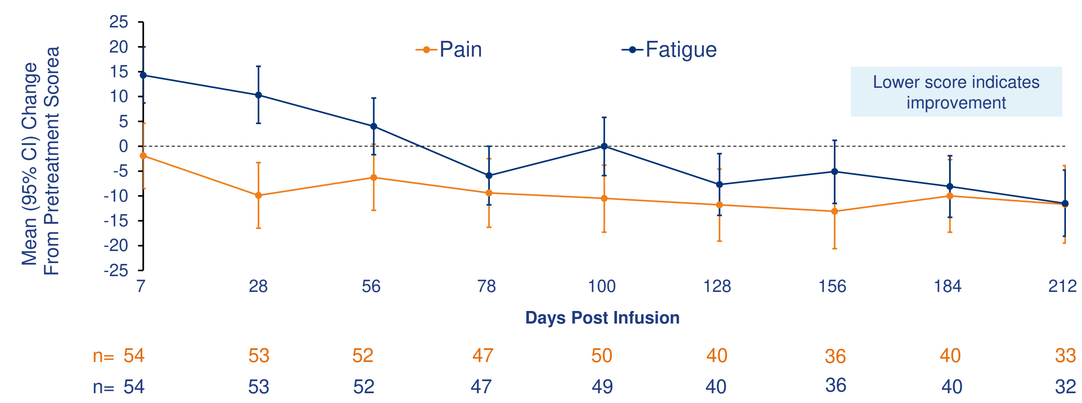
RESULTS (*CONTD.*)

Figure 3. Improvement in Physical Functioning and GHS Over Time



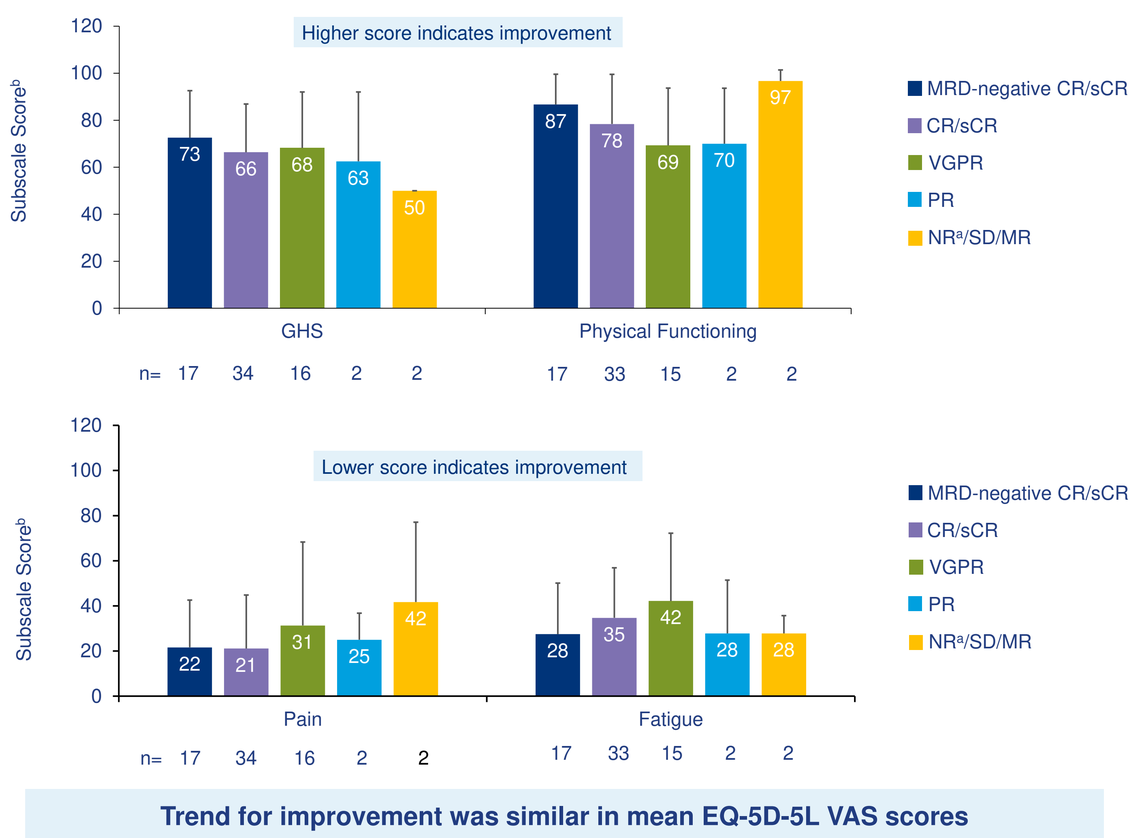
[a]Mean changes from pretreatment score analyzed using repeated-measures mixed-effects models. CI, confidence interval. GHS, global health status.

Figure 4. Improvement in Pain and Fatigue Over Time



[a]Mean changes from pretreatment score analyzed using repeated-measures mixed-effects models. CI, confidence interval

Figure 5. Improvement in Overall HRQoL, Pain, and Fatigue at Day 100 Post Infusion by Treatment Response



[a]One patient with progressive disease excluded due to lack of interviews. [b]Values are mean ± standard deviation. CR, complete response; EQ-5D-5L, EuroQol 5-dimensional 5-level; GHS, global health status; HRQoL, health-related quality of life; MR, minimal response; MRD, minimal residual disease; NR, no Response; PR, partial response; sCR, stringent CR; SD, stable disease; VAS, Visual Analogue Scale; VGPR, very good PR.

CONCLUSIONS

- Patients with heavily pretreated MM showed rapid and clinically meaningful improvements in HRQoL after cilta-cel infusion.
  - Improvements in pain, fatigue, physical functioning, general health status, and disease-related health status were consistent with their clinical outcomes.
- Trend for HRQoL improvements with increased depth of response suggest further HRQoL benefits could be expected as responses may deepen over time with cilta-cel.
- Limitations
  - Patient-reported outcomes were based on a relatively small sample size.
  - The results presented are exploratory and descriptive summary of patient’s self-reported outcomes.

REFERENCES

1. Johnson AT, et al. *Eur J Haematol* 2009;83(2):139-48; 2. Madduri D, et al. ASH 2020, Abstract #177.

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Previously presented at ASH 2020