LONG TERM FOLLOW-UP OF ZEVOR-CEL IN PATIENTS WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA

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22nd Annual MEETING & EXPOSITION
September 17-20, 2025 • Toronto, Canada
International Myeloma Society

INTRODUCTION

- Zevorcabtagene autoleucel (zevor-cel) is a B-cell maturation antigen (BCMA) targeting, fully human, autologous, chimeric antigen receptor (CAR) T-cell therapy which has been approved in China since 2024 for the treatment of patients with relapsed or refractory multiple myeloma (RRMM).
- Phase 1 of LUMMICAR STUDY 1 was conducted in China (NCT03975907) evaluating zevor-cel in patients with RRMM.
- Previously disclosed 3-year follow-up data (ASH 2023 Abstract 4845) demonstrated maintained deep and durable responses, with 72.7% and 53.0% of CR/sCR patients being event-free at 24 and 36 months after infusion, alongside a tolerable safety profile in 14 patients.

AIM

- To present the updated result on the safety and efficacy of zevor-cel from Phase 1 study with a longer follow up.

METHOD

- This was a single-arm, open-label study conducted at five sites in China. Patients with RRMM who had received ≥ 3 prior regimens including a proteasome inhibitor and an immunomodulatory agent with an eastern cooperative oncology group (ECOG) score of 0 or 1 were enrolled. Zevor-cel was administered as a single infusion of 100×10^6 or 150×10^6 CAR+ T cells.
- The primary endpoints were safety and the secondary endpoints included efficacy and pharmacokinetics.
- Response was assessed per the international myeloma working group (IMWG) 2016 criteria.

RESULTS

Patient Characteristics

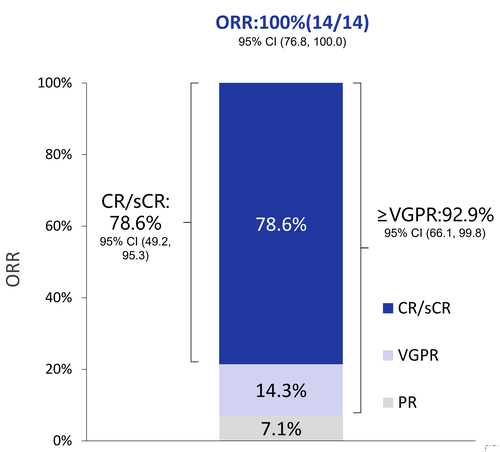
Baseline characteristic	N=14
Age, median (range), y	54.0 (34, 62)
Sex	
Men, n(%)	7 (50.0%)
Women, n(%)	7 (50.0%)
Years since diagnosis, median (range)	4.7 (1.2, 8.7)
Number of prior regimens	6.0 (3-11)
Proteasome inhibitors	14 (100%)
Immunomodulatory drugs	14 (100%)
Autologous	11 (78.6%)
ECOG	
0	7 (50%)
1	7 (50%)
International Staging System, n(%)	
I or II	12 (85.7%)
III	2 (14.3%)
Cytogenetic high risk, n(%)	7 (50%)
Extramedullary plasmacytoma, n(%)	2 (14.3%)
Bone marrow plasma cells, Median (range), (%)	38.00 (0.5, 70)
BCMA Expression Rate, Median (range), (%)	42.75 (5.4, 99.7)

Safety Summary

Adverse event	N=14, n (%)
Treatment-related AEs (TRAEs)	14 (100%)
Grade 3/4 hematologic TRAEs	14 (100%)
Cytokine release syndrome (CRS), any grade	13 (92.9%)
Grade 1	9 (64.3%)
Grade 2	4 (28.6%)
Grade 3/4/5	0
Grade ≥3 neurologic TRAEs	0
ICANS, any grade	0
Grade ≥3 infection and infestation TRAEs	3 (21.4%)
Grade 3	3 (21.4%)
Grade 4	0
All serious adverse events (SAE)	3 (21.4%)
Treatment-related SAE	2 (14.3%)
Death due to TRAE	0

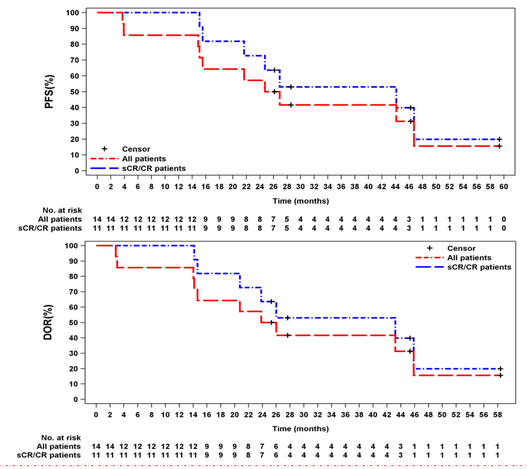
- 13 (92.9%) patients experienced grade 1 or 2 CRS.
- No immune effector cell-associated neurotoxicity syndrome, delayed neurotoxicities, second primary malignancy, or other delayed adverse events was observed.
- 3 patients died at month 32.6, 42.5 and 48.5, respectively; none were related to zevor-cel.

Efficacy Summary



- Between July 23, 2019 and July 10, 2020, 14 patients with a median age of 54 years received a single infusion of zevor-cel (100×10^6 CAR+ T cells in 3 patients, 150×10^6 CAR+ T cells in 11 patients).
- As of February 22, 2025, the median follow-up duration was 53.3 months (range:14.8, 63.5).
- Within the subjects achieving CR/sCR, MRD negativity ($<10^{-5}$) was observed in 11 patients, accounting for 100%.
- 1 patient remained in sCR at 59.3 months in the study.

Kaplan-Meier Plot of PFS and DOR



- The median PFS was 25.8 (95% CI; 14.9, 46.7) months in all subjects and 44.1 (95% CI; 15.5, NE) months in CR/sCR patients;
- The median DOR was 24.9 (95% CI; 14.0, 45.9) months in all subjects and 43.2 (95% CI; 14.6, NE) months in CR/sCR patients;
- The median overall survival (OS) was not reached.

Month /Rate	24m (95%CI)	36m (95%CI)	48m (95%CI)	60m (95%CI)
PFS	57.1% (28.4, 78.0)	41.7% (16.4, 65.4)	15.6% (1.2, 46.2)	
DOR	50.0% (22.9, 72.2)	41.7% (16.4, 65.4)	15.6% (1.2, 46.2)	
OS	100% (100, 100)	92.3% (56.6, 98.9)	84.6% (51.2, 95.9)	76.9% (44.2, 91.9)

CONCLUSIONS

- In this open-label, multi-center, phase 1 clinical study in patients with RRMM, with approximately 5 years of follow-up, zevor-cel reaffirms the results with a manageable safety profile and compelling efficacy in RRMM.

REFERENCES

- Chen W, Fu C, Cai Z, et al. Sustainable Efficacy and Safety Results from LUMMICAR STUDY 1: A Phase 1/2 Study of Fully Human B-Cell Maturation Antigen-Specific CAR T Cells (CT053) in Chinese Subjects with Relapsed and/or Refractory Multiple Myeloma. Blood 2021; 138 (Supplement 1): 2821.
- Fu C, Chen W, et al. Three-year Follow-up on Efficacy and Safety Results from Phase 1 LUMMICAR STUDY 1 of Zevorcabtagene Autoleucel in Chinese Patients with Relapsed or Refractory Multiple Myeloma. ASH 2023, Abstract#4845.

ACKNOWLEDGEMENT

- All patients who participated in this study, their families and caregivers
- The physicians and nurses who cared for patients and supported this study
- Staff members involved in data collection and analysis

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