SAFETY, TOLERABILITY AND CLINICAL ACTIVITY OF ANITO-CEL IN RRMM

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BACKGROUND

Chimeric antigen receptor T-cell (CAR-T) therapy targeting BCMA has transformed the treatment of relapsed/refractory multiple myeloma (RRMM). Anitocabtagene autoleucel (anito-cel) is an autologous anti-BCMA CAR-T therapy with a novel D-domain binder used to treat patients with RRMM. Here, we report the safety, tolerability, and clinical activity of anito-cel across phase 1 and phase 2 portions of the iMMagine-1 trial.

RESULTS

	iMMagine-1 Phase 1	iMMagine-1 Phase 2
Characteristics		
Patients treated, N	38	58
Median age, years (range)	66 (44-76)	66 (38-77)
Median prior lines of therapy (range)	4 (3-16)	4 (3-8)
Triple-class refractory, n (%)	38 (100)	40 (69)
Penta-class refractory, n (%)	26 (68)	20 (34)
Efficacy Outcomes		
ORR, n (%)	38 (100)	55 (95)
CR/sCR, n (%)	30 (79)	36 (62)
MRD-negative, n (%)	25 (89)[a]	36 (92)[b]
Median follow-up, months (range)	34 (21-52)	10.3 (2.0-17.8)
PFS, months (%)	9 (92); 18 (65); 27 (52)	6 (90)
OS, months (%)	9 (27); 18 (82); 27 (78)	6 (95)
Safety		
CRS, any grade, n (%)	36 (95)	49 (84)
ICANS, any grade, n (%)	7 (18)	5 (9)
ICANS, grade 3, n (%)	2 (5)	1 (2)

Footnote: CR: Complete response; sCR: Stringent complete response; ICANS: Immune effector cell-associated neurotoxicity syndrome
[a] Evaluable for MRD negativity at 10^{-5} (n=28)
[b] Evaluable for MRD negativity at 10^{-5} (n=39)

Table 1. Composite Data for IMMagine-1 Phase 1 and 2

METHODS

Eligible patients had RRMM with ≥3 prior lines of therapy (including proteasome inhibitors, immunomodulatory drugs, and anti-CD38 antibody). Patients received a single infusion of anito-cel following standard lymphodepletion (fludarabine and cyclophosphamide). Compared results from both iMMagine-1 trials thus far.

DISCUSSION

Evaluated 96 heavily pretreated patients with RRMM (Phase 1: n=38; Phase 2: n=58) with a median of 4 prior lines of therapy.
High baseline disease burden with triple-class refractory disease present in 100% (Phase 1) and 69% (Phase 2) of patients, alongside penta-class refractoriness in 68% and 34%, respectively.

Demonstrated robust clinical activity, reaching an ORR of 100% in Phase 1 and 95% in Phase 2, with deep complete responses (CR/sCR: 79% vs. 62%).

Deep responses corresponded with high MRD negativity rates of 89% (Phase 1) and 92% (Phase 2) among evaluable patients.
Durability was preserved across cohorts: 27-month PFS and OS rates reached 52% and 78% in Phase 1 (median follow-up: 34 months), while Phase 2 showed 6-month PFS and OS rates of 90% and 95% (median follow-up: 10.3 months).

Manageable safety profile across phases, with CRS occurring in 95% of Phase 1 and 84% of Phase 2 patients.

Neurotoxicity was infrequent and mostly low-grade; any-grade ICANS occurred in 18% (Phase 1) and 9% (Phase 2), with Grade >=3 ICANS remaining low at 5% and 2%, respectively.

CONCLUSION

Anito-cel continues to demonstrate a manageable safety profile and deep, durable responses in patients with RRMM. The consistency of high MRD-negativity rates and prolonged PFS across both phases supports its potential as a highly efficacious BCMA-targeted therapy. BCMA: B-cell maturation antigen, CD: cluster of differentiation, CR: complete response, ICANS: immune effector cell–associated neurotoxicity syndrome, MRD: measurable residual disease, OS: overall survival, PFS: progression-free survival, sCR: stringent complete response

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