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Real world data of the safety and efficacy of Talicabtagene autoleucel (Humanized CD19 CAR-T) in relapsed/refractory B-acute lymphoblastic leukemia from India

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INTRODUCTION

- Talicabtagene autoleucel (Tali-cel), a second generation CD19-directed humanized CAR-T cell therapy is the first CAR-T cell therapy approved in India for relapsed/refractory B-cell malignancies.(1-5)
- Pre-clinical studies showed remarkable efficacy and toxicities.(5)
- Phase I/II clinical trials shows excellent efficacy and safety profile.(1-5)

AIM

To analyse the safety and efficacy of the patients with r/r B-acute lymphoblastic leukemia (B-ALL), aged ≥ 15 years who received Tali-cel as a part of standard-of-care.

METHODS

Study Design

Patient Population: Patients aged ≥ 15 years B-acute lymphoblastic leukemia (ALL) were enrolled at were enrolled at 37 centres across India.

Dosing Protocol: A single infusion(Day 0) at a target dose of ≥ 5x10^6/kg, following conditioning(Day -5 to -3) with either Flu-Cy or bendamustine.

Efficacy: Objective Response Rate (ORR) by BM assessment.

Safety: Adverse events of special interest, including Cytokine Release Syndrome (CRS), Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), Immune Effector Cell-Associated Hemophagocytic Lymphohistiocytosis (IEC-HS) as per ASTCT criteria.

RESULTS

- A total of 135 patients were enrolled and leukapheresed from 15/11/2023 to 30/04/2025 and 105 patients evaluated for efficacy.
- ORR in the B-ALL cohort was 88% with CR rate of 86%.

Table-1: Baseline Characteristics

Characteristics of Patients (n=135)	n (%)
Gender	
Male n (%)	101 (75%)
Female n (%)	34 (25%)
Age Median (range)	26 (15-78)
Blast % Median (range)	2 (0-96)
Lines of therapy Median (range)	2 (1-5)

Fig-1: Consort Diagram

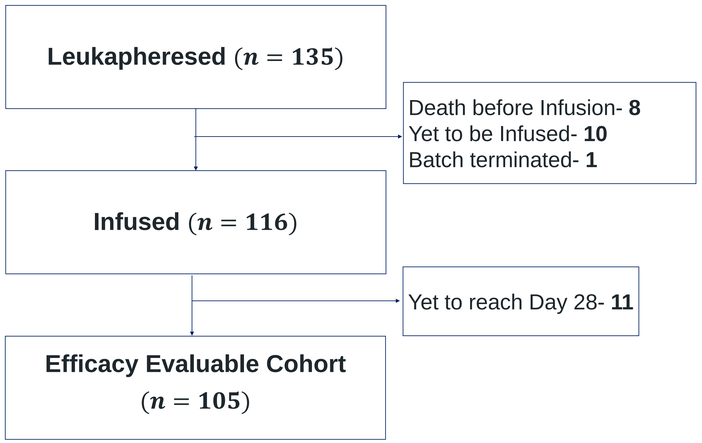


Fig-2: Responses

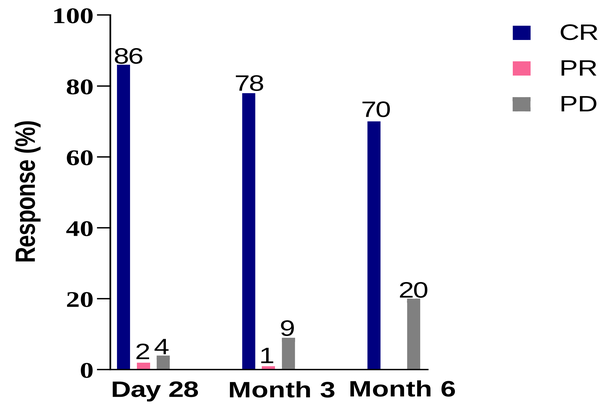


Table-2: Adverse Events of Special Interest

Toxicities	n (%) (n= 105)
Cytokine Release Syndrome	
Grade III/IV	5 (5%)
All Grades	76 (72%)
ICANS	
Grade III/IV	5 (5%)
All Grades	10 (9%)
Hypogammaglobulinemia	
All Grades	55 (52%)
IEC-HS	
All Grades	22 (21%)

Fig-3: Progression Free Survival Curve

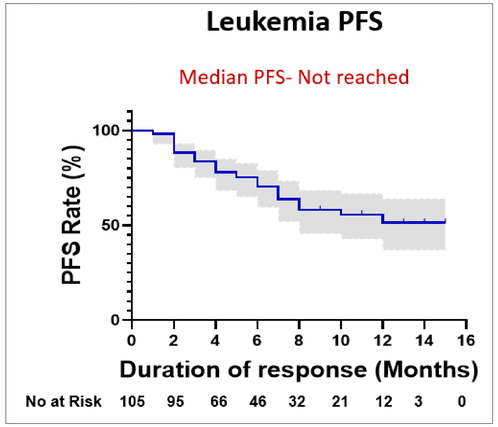
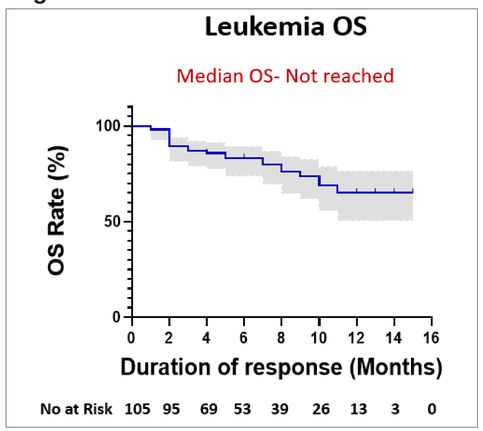


Fig-4: Overall Survival Curve



CONCLUSIONS

The real-world experience confirms the safety and establishes the efficacy as a definitive therapy without the need for consolidation alloSCT in relapsed/refractory B-ALL.

REFERENCES

1. Jain Hasmukh, et al. The Lancet Haematology (2025) 12(4):e282-93.
2. Karulkar, Atharva, et al. Blood 142 (2023): 257.
3. Jain, Hasmukh, et al. Blood 142 (2023): 4838.
4. Karulkar, Atharva, et al. Blood 140 (2022): 4610-4611.
5. Jain, Hasmukh, et al. Blood 140 (2022): 10332-10334.
6. Dwivedi Alka, et al. Molecular Cancer Therapeutics (2021);20(5):846-58

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