Real world data of novel Talicabtagene autoleucel (humanized CD19 CAR-T) from India; ensuring equitable access with excellent safety and efficacy profile

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BACKGROUND

Talicabtagene autoleucel (Tali-cel) is India's first indigenous, affordable and humanized anti-CD19 CAR-T cell therapy.

Commercial authorization was granted by CDSCO (Indian regulatory agency) in October 2023 for relapsed/refractory (r/r) B-cell malignancies.

OBJECTIVES

To evaluate the real-world feasibility, access, efficacy, and safety of Tali-cel for relapsed/refractory (r/r) B-cell malignancies.

To develop a sustainable and efficient system for delivering CAR-T therapy in India, especially in limited resource settings.

CONCLUSION

Real-world evidence underscores Tali-cel's efficacy and safety in r/r B-cell malignancies, enabling its effective clinical delivery and manufacturing success beyond trial settings in India.

METHODS

Study Design

Patient Population: Patients aged ≥ 15 years with r/r B-cell malignancies, specifically B-cell lymphomas (BCL) and acute lymphoblastic leukemia (ALL).

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

Administration and Coordination

Cancer Centers: Treatment was administered at specialized cancer centers trained in CAR-T management.

Manufacturing Feasibility and Access

Scheduling: A central unit coordinated monthly manufacturing slots based on:

- Request initiation time
- Patient health & disease status
- Financial considerations

Manufacturing Success Rate (MSR)

Out-of-Specifications (OOS) Rate

Vein-to-Vein Time

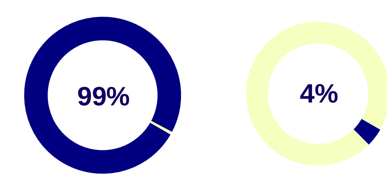
Efficacy : Objective Response Rate (ORR) by PET-CT or BM assessment

Safety: Specific adverse events of 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

Manufacturing Feasibility and Access

- **Average Slot wait time : ≤ 15 days**
- **Average Manufacturing turn-around time : 15 days**
- **Median vein to vein time : 26 days**



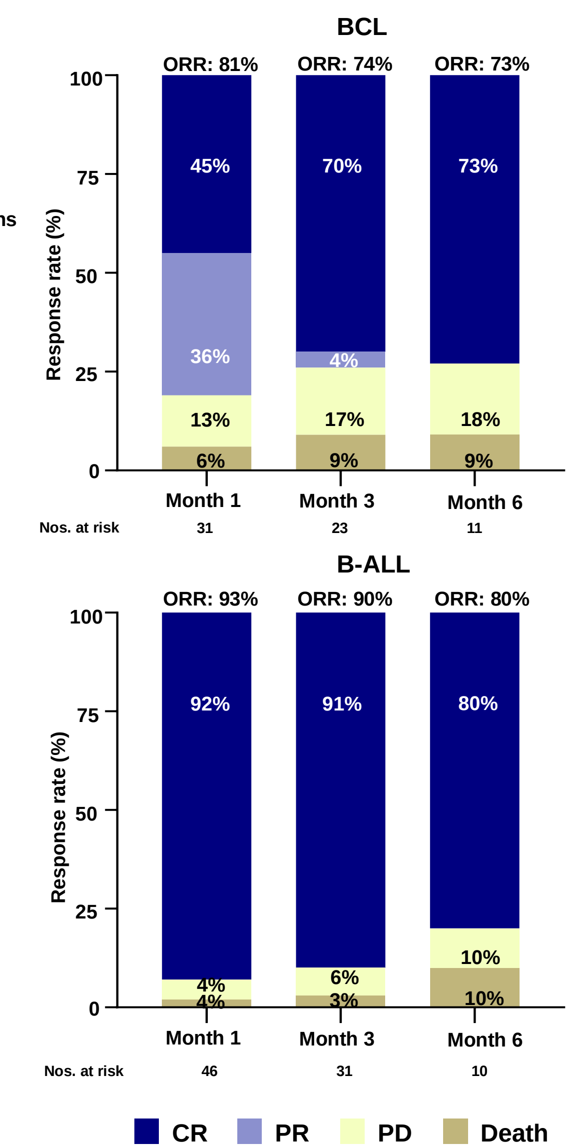
Manufacturing success rate (MSR)

Out-of-specifications rate (OOS-R)

Patient characteristics

Characteristics	All patients (n=108)	BCL (n=50)	B-ALL (n=58)
Age, years			
Median(range)	35 (15-81)	56 (17-81)	23(15-64)
Sex, n(%)			
Male	76 (70%)	34 (68%)	42 (72%)
Female	32 (30%)	16 (32%)	16 (28%)
Prior Line of therapy, numbers			
Median (range)	3 (1-7)	3 (1-7)	3 (1-6)
Disease burden, n(%)			
Bulky	NA	13 (26%)	NA
Non-bulky	NA	37 (74%)	NA
% blast			
Median (range)	NA	NA	2% (0-94)
No. of patients infused at data cut off date	89	39	50
No. of patients evaluable at data cut off date	77	31	46

Efficacy



Safety

Toxicities, n(%)	All patients (n=77)	BCL (n=31)	B-ALL (n=46)
CRS			
Grade III/IV	3 (4%)	1 (3%)	2 (4%)
All Grades	62 (81%)	25 (81%)	37 (80%)
ICANS			
Grade III/IV	2 (3%)	2 (6%)	0 (0%)
All Grades	5 (6%)	3 (9%)	2 (4%)
Hypogammaglobulinemia			
All Grades	38 (49%)	19 (61%)	19 (41%)
IEC-HS			
All Grades	12 (16%)	4 (13%)	8 (17%)

HCRU for CAR-T management

Key Healthcare Resource Utilization (HCRU), n(%)	All patients (n=77)	BCL (n=31)	B-ALL (n=46)
Facility			
ICU admissions	6 (8%)	2 (6%)	4 (9%)
Drugs for AEs management			
Tocilizumab	51 (56%)	18 (58%)	33 (72%)
Corticosteroids	9 (12%)	4 (13%)	5 (11%)
Anakinra	11 (14%)	4 (13%)	7 (15%)
Vasopressors	6 (8%)	3 (10%)	3 (7%)
IVIG	36 (41%)	17 (55%)	19 (41%)

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