

Development of equitable access model for nationwide implementation of affordable CAR-T cell therapy in India: a real-world experience

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BACKGROUND

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

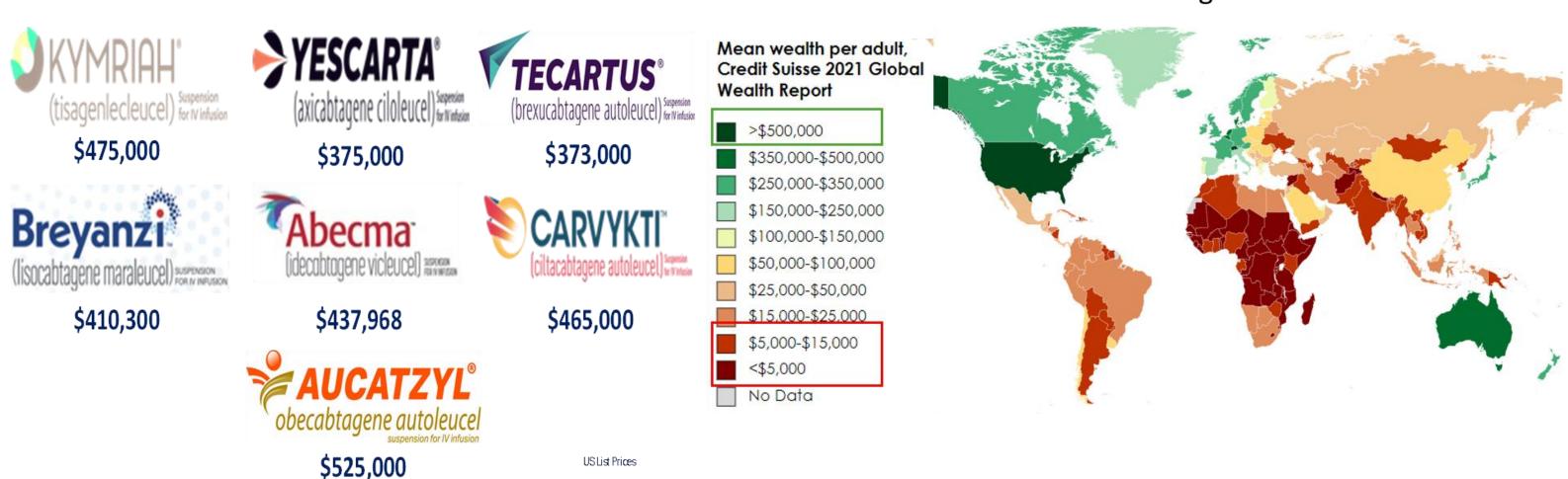
Commercial authorization was granted by CDSCO (Indian regulatory agency) in October 2023 for relapsed/refractory (r/r) B-cell malignancies.

Barriers to access CAR-T cell therapy in LMICs

Financial burden and affordability gap

Exorbitant drug costs

Lack of income and insurance coverage

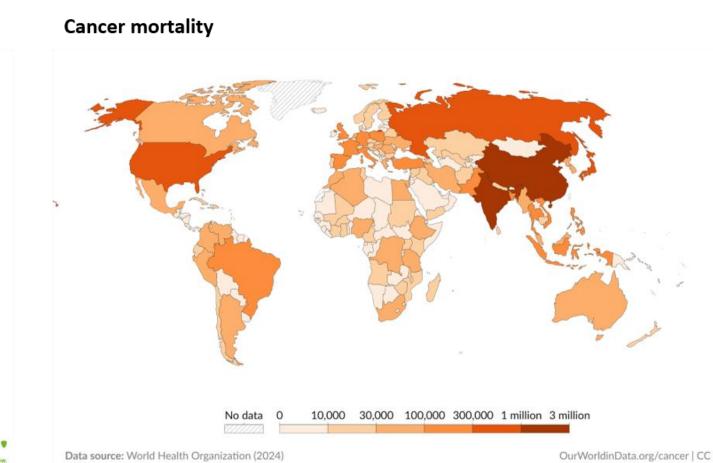


Geographic Disparity in LMICs

 Unavailability of CAR-T cell therapy as well as other curative strategies²

70% of global cancer deaths in LMICs^{3,4}





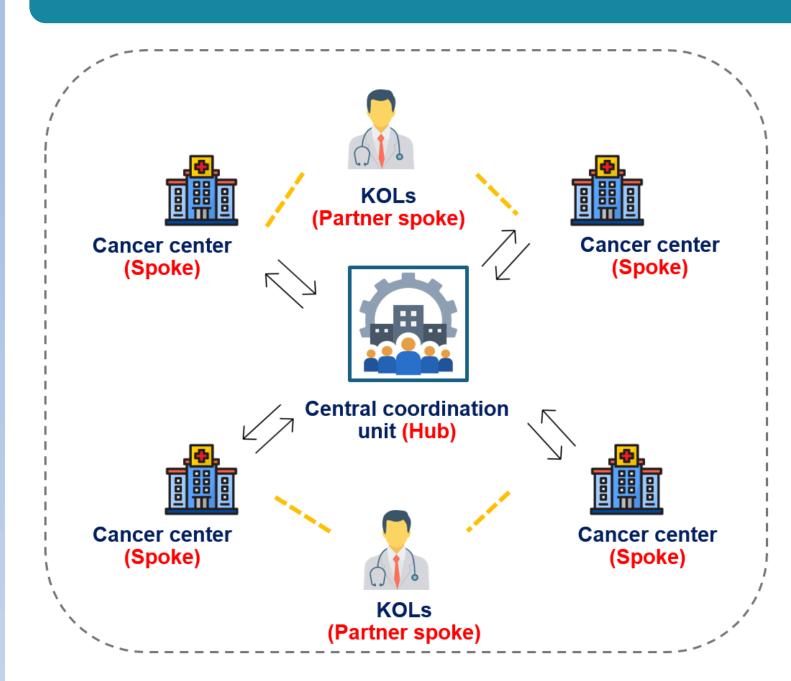
OBJECTIVES

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.

METHODS

Elements of equitable access model – orchestrated Hub and Spoke model



Hubs: GMP units + CART manufacturing **Spokes**: Centers for diagnosis, follow-up and monitoring

Co-ordination Units fort slot allocation, quality assurance and pharmacovigilance

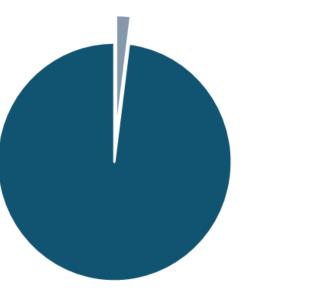
Overall Manufacturing success rate(MSR) – 98%

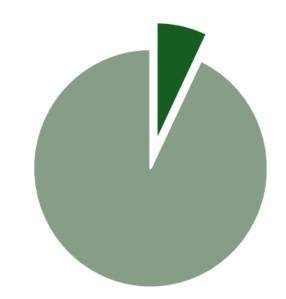
Equitable access model allowed for failure-free logistics independent of tier status

RESULTS

Equitable access model supports centralized manufacturing

- · Centralized manufacturing supports better resource management, process control and product quality and can lower manufacturing costs





98% MSR 7% required more than one attempt at mfg.

7% required repeat apheresis.

Affiliation and accreditation across diverse geography

Tier II

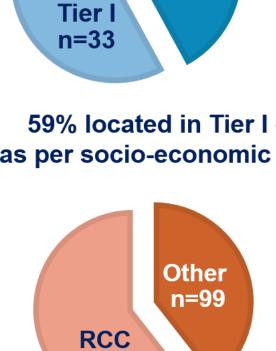
57

Cancer centers affiliated, trained and actively treating patients with Tali-cel since October 2023

Gol recognized regional cancer

centers for providing affordable,

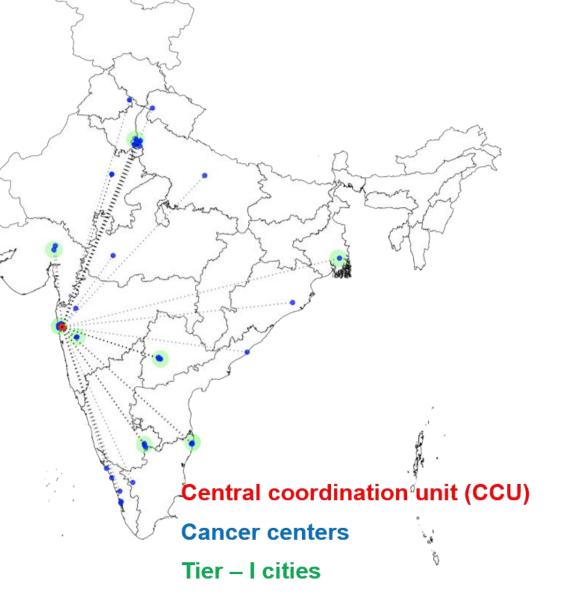
comprehensive cancer care



n=152



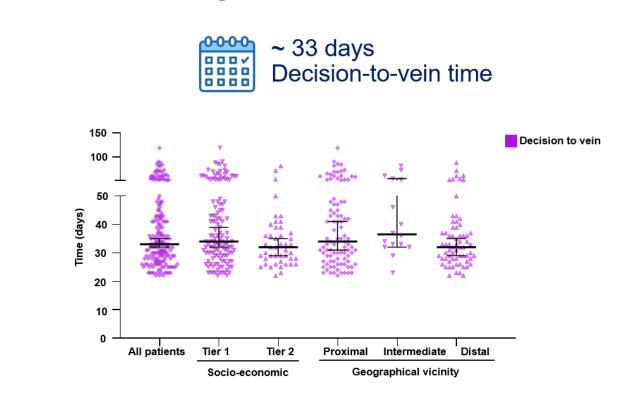
61% patients in regional cancer centers (RCC)

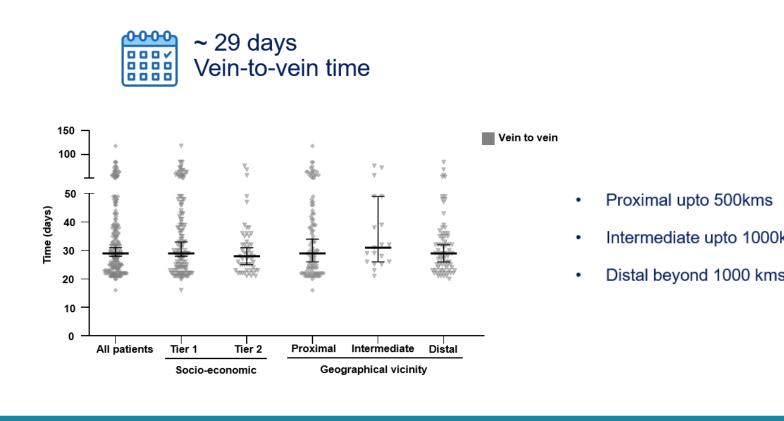


Intermediate upto 1000kms

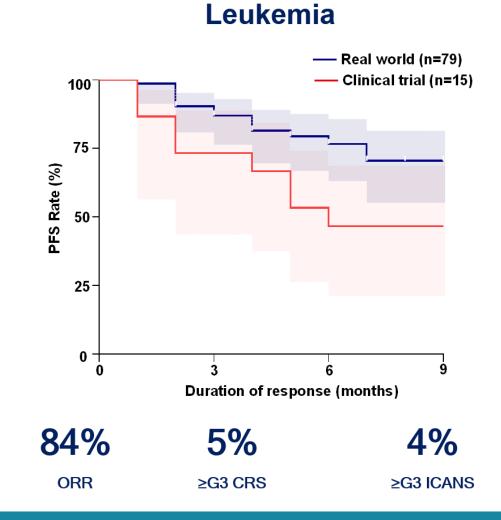
Accessibility of CAR-T cells in timely manner to all

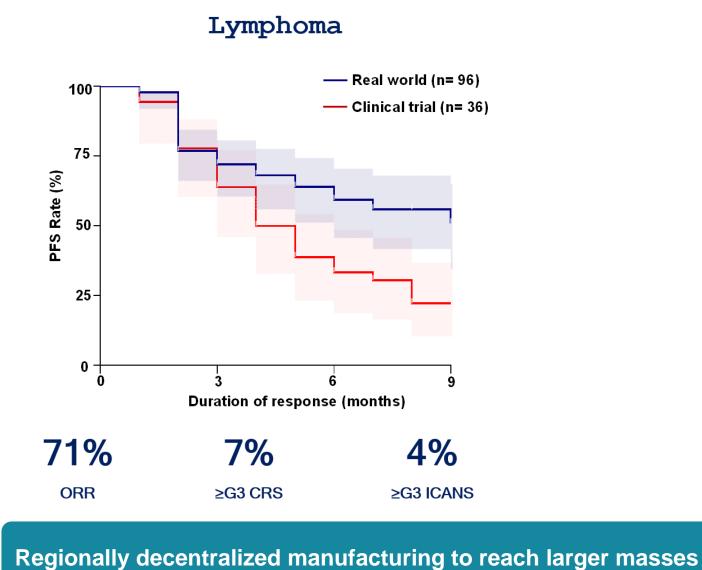
• Equitable access model allowed for access to CAR-T independent of tier status and geographical vicinity to the manufacturing site





Tali-cel – Efficacious and safe as standard of care in real world





Easy to deliver as outpatient like standard of care in real world

Current GMP facility	New GMP facility

Lymphoma	Leukemia
7	12
days, median hospitalization	days, median hospitalization
7%	5%
ICU admission rate	ICU admission rate
15	4
days, median ICU stay	days, median ICU stay

Utilization: 400 patients >80% capacity utilization within two years of market approval

Capacity: 480 patients

Utilization: for accessible and affordable CAR-T cell therapy in India and other **LMICs**

Capacity: >3000 patients

CONCLUSION

- Talicabtagene autoleucel shows favorable balance of efficacy to toxicity.
- Talicabtagene autoleucel is easy to deliver with limited resources in outpatient-like settings
- Equitable access model developed
 - allows access across Tier-I and Tier-II cities.
 - allows access across diverse geographies independent of vicinity to manufacturing site.
 - allows timely delivery to the patients across various large and small cancer centres.

REFERENCES

²https://www.susupport.com/knowledge/cell-gene-therapy/whichcountries-cell-therapy-available ³Cornetta, Kenneth, et al. "Gene therapy access: global challenges, opportunities and views from Brazil, South africa, and India."

Molecular Therapy (2022). ⁴Sung, Hyuna, et al. "Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries." CA: a cancer journal for clinicians 71.3 (2021): 209-249. ⁵Cortes, Javier, et al. "Enhancing global access to cancer

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 - TMC Mumbai and ImmunoACT
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