

India's First CAR T-Cell Therapy Shows Durable Results: Two-Year Remission Achieved in Blood Cancer Patients

- *Breakthrough data from Immuneel Therapeutics shows sustained remission in multiple patients treated with Varnimcabtagene autoleucel (IMN-003A)*
- *Seven patients surpass two-year progression-free survival (PFS), a national first known for Indian CAR T therapy*
- *Benchmark response rates recorded with 83% ORR at Day 90 and 50% at Day 365*
- *Over 50 patients treated to date with improved outcomes and a favorable safety profile*

Bengaluru, August 9, 2025: In a major milestone in Indian oncology care, **Immuneel Therapeutics'** Made-In-India CAR T-cell therapy has delivered the country's first known long-term remission in patients with aggressive blood cancers. Seven patients treated in 2022 have now surpassed two years of progression-free survival (PFS), a first for any made-in-India CAR T-cell therapy. This achievement reinforces the durability of Immuneel's approach and its potential to transform outcomes for patients with aggressive blood cancers.

The CAR T-cell therapy, known as **Varnimcabtagene autoleucel (IMN-003A)**, under Immuneel's IMAGINE Phase 2 clinical trial, aimed at treating adult patients with relapsed or refractory CD19-positive B-cell Non-Hodgkin Lymphoma (B-NHL) which is among the most aggressive forms of blood cancer, and many patients do not respond to standard therapies. In India, access to next-generation treatments like CAR T-cell therapy has been limited by cost and infrastructure, until now.

The encouraging results of the therapy recorded an 83% overall response rate (ORR) at Day 90 and a 50% ORR at Day 365, with a complete response rate of 83%, placing it among the highest reported outcomes in Indian clinical benchmarks for CAR T-cell therapies. The therapy has now been administered to more than 50 patients in India, marking Immuneel's successful scale-up in delivering this complex therapy with consistent outcomes and a favorable safety profile.

Ms. Kiran Mazumdar-Shaw, Board Director & Co-Founder, Immuneel Therapeutics said, *"This milestone is a powerful validation of our vision to make cutting-edge cancer therapies accessible and affordable for patients. The fact that we now have long-term survivors, treated with a Made-in-India CAR T therapy, it's a testament to the real, life-changing impact innovation can have on patients and their families. It reaffirms that innovation rooted in local context can deliver globally benchmarked outcomes. This achievement strengthens India's positioning as a frontrunner in delivering high-impact cancer innovations, aligning with the broader national vision of becoming a global healthcare leader by 2047."*

Mr. Amit Mookim, Board Director & CEO, Immuneel Therapeutics, added, *"This achievement is not just a clinical validation, but a strategic proof point of what's possible when world-class science is built for India and beyond, in India. Crossing the two-year progression-free survival mark with multiple patients demonstrates that India can lead in delivering durable, next-generation therapies. At Immuneel, our*

focus remains on scaling access, deepening impact, and continuing to redefine what cancer care can look like for patients and families in India and beyond India.”

Globally, CAR T therapies are considered revolutionary but are often expensive and logistically challenging. Immuneel’s effort marks a turning point in making these advanced treatments accessible to Indian patients, particularly those who have exhausted other options.

Key Clinical Highlights:

- **India’s Longest-Known CAR T Therapy Survivors: Seven** patients enrolled in the Phase 2 IMAGINE trial have crossed the two-year PFS milestone, a first for any Indian CAR T therapy, underscoring durable remission and the potential for improved long-term survival
- **Strong and Sustained Response Rates:** IMN-003A (clinical trial) showed an 83% ORR at Day 90, a 50% ORR at Day 365, and a Complete Response rate of 83%, setting new standards in treatment for relapsed/refractory CD19+ B-NHL
- **50-Patient Milestone:** Therapy has been successfully administered to more than 50 patients across leading Indian hospitals, demonstrating consistent clinical outcomes, favorable safety profile, and Immuneel’s ability to scale complex cell therapy delivery nationally
- **Backed by DBT-BIRAC Grant:** The IMAGINE Phase 2 trial was supported by BIRAC (Biotechnology Industry Research Assistance Council) under the Department of Biotechnology’s BIPP scheme, underscoring national recognition of its scientific merit

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About the IMAGINE Study

The IMAGINE Phase 2 trial was launched in 2022 to evaluate the safety and efficacy of Varnimcabtagene autoleucl (IMN-003A) in relapsed and refractory CD19-positive B-cell malignancies.

Trial Details:

- Clinical Trial Registry Number: CTRI/2022/03/041162
- Study Sites:
 - Narayana Health- Mazumdar Shaw Medical Center, Bangalore
 - Apollo Cancer Center, Chennai
 - PGIMER, Chandigarh

The study confirmed the therapy’s favorable safety profile with no ICU admissions or severe neurotoxicity, and demonstrated durable responses with significant improvements in patient’s quality of life

About Immuneel Therapeutics (Immuneel)

Immuneel is a pioneering start-up company leading the change in cell & gene therapies and personalized immunotherapy for patients in India. Headquartered in Bengaluru, India – a research-led, fully integrated

cell & gene therapies company committed to bringing breakthrough cancer treatments to India, affordably & build a portfolio of next generation cell therapies. Additional information about Immuneel is available at www.immuneel.com.

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