

Startup of the year 2024- ImmunoACT

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Emerging Leader in Cell & Gene Therapy



Spun-out from the Indian Institute of Technology Bombay (IIT-B) in 2018, ImmunoACT is India's pioneer in the development of the country's first indigenous Cell & Gene Therapy. Dr Rahul Purwar and Dr Atharva Karulkar started ImmunoACT with a mission to provide affordable access to novel autologous Chimeric antigen receptor or CAR-T cell therapies.

Both the founders were well aware that despite the expanding burden of cancer in India, many new cancer treatments are inaccessible because of their high cost and the general lack of insurance coverage among people in India. In addition, some treatments, including CAR T-cell therapy, can cause severe side effects that must be treated in a hospital, further driving up the costs of treatment and requiring access to a nearby hospital.

A significant push in their entrepreneurial journey came in 2017 when the first CAR-T cells were approved by the United States Food and Drug Administration (US FDA). But the huge cost associated with it, i.e. approx. Rs 3-4 crore per patient, emerged as a huge challenge. Thereafter, Dr Rahul Purwar and his team set out their plans to develop an affordable treatment option i.e. Made in India and Made for India.

However, a roadblock for Dr Purwar's team was the lack of a precedent in India, without any reference, background material or techniques. Thus, they relied solely on papers published by companies and universities in the US, trying to understand and replicate their efforts.

The Society for Innovation and Entrepreneurship (SINE) at IIT-Bombay further guided the team through crucial steps, like team structure, business plan development, incorporation, audit requirements, and connecting with industry experts to evaluate their work's viability. SINE also provided an initial funding of Rs 5 lakh and a space for ImmunoACT team to set up their first lab.

In particular, Dr Rahul Purwar has been a guiding force in the startup's journey, driven by his clear vision of focusing on science for society rather than commercial success. His commitment to scientific excellence and integrity has been the foundation for the entire team, that led ImmunoACT to develop India's first domestic CAR-T cell therapy, NexCAR19, commercially approved by the Central Drugs Standard Control Organisation (CDSCO) in 2023, priced at roughly Rs 30-40 lakh per patient which is just 1/10th of the international price.

India witnesses around 25,000 B-cell lymphoma patients annually, and this treatment will be accessible in multiple government and private hospitals across major cities. *"CAR-T cell therapy, developed indigenously, is a type of cancer immunotherapy that involves genetically modifying T cells in a laboratory setting to enhance their ability to identify and eradicate cancer cells. This innovative therapy offers new hope to patients in India and resource- constrained nations", said Dr Purwar.*

"An important aspect to consider when talking about cell and gene therapy is the accessibility of the therapies. Only 10 per cent of our population can afford these therapies. Including our cell and gene therapies in government healthcare access programmes, such as Ayushman Bharat and reduction in the high GST on oncology therapies, can make cell and gene therapies affordable", he added.

NexCAR19 is the culmination of a collaborative effort across a decade, between the IIT Bombay, and Tata Memorial Centre (TMC). Hyderabad-based Laurus Labs has been the early backer of ImmunoACT and has invested over \$18 million to support the startup to scale its R&D and commercialisation efforts. Laurus Labs' investment in ImmunoACT has supported the startup in successfully creating GMP manufacturing facility along with state-of-the-art R&D facility at Navi Mumbai and for conducting Phase II study at various hospitals including Tata Memorial Hospital (TMH).

Borne from academia-industry partnership, ImmunoACT is a perfect example of private public partnership in India. *On this note, Dr Purwar says, "Innovation in India and indigenous production through solid public-private partnerships (PPP) across Indian academia and industry can prove to be important for bringing down costs."*

Experts at TMH who oversaw a multicentre Phase I/II pivotal clinical trial involving 60 relapsed/refractory B-cell lymphoma and leukaemia patients, reported remarkable results with an overall response rate (ORR) of approximately 70 per cent. This therapy demonstrates a favourable balance between efficacy and toxicity, making it a promising option for patients with the CD19 marker in B cells, a protein commonly associated with B-cell-related cancers such as B-cell lymphomas, acute lymphoblastic leukaemia, and chronic lymphocytic leukaemia.

Another major focus of the startup had been on retaining ownership of IP. As a result, ImmunoACT evolved its entire value chain in India, from the plasmid, to the vector, and all the way to the final CAR construct.

Moving forward, the startup is increasing the reach of the product to different states in India and across the globe; for instance, ImmunoACT has recently signed a Memorandum of Understanding (MoU) with the government in Mexico. The objective is to target countries with similar economies, like India, where there is a need for CAR-T therapies, like in Africa and Europe. ImmunoACT plans to tie up with some local pharma companies in those countries that will assist in the logistics.

As a part of its future plans, the startup is also actively engaging with stakeholders to develop CAR-Ts for non-oncology indications, to move beyond cancer, and touch upon areas such as sickle cell anaemia and other diseases, where immune cells can help in providing therapeutic effects.