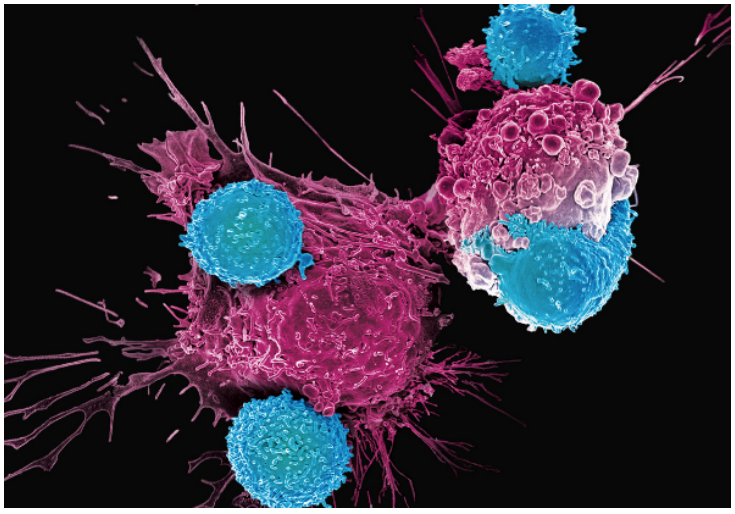
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ImmunoACT announces CDSCO approval of Indiaâ??s first CAR-T cell therapy NexCAR19

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For the treatment of r/r B-cell lymphomas and leukemia



Immunoadoptive Cell Therapy (ImmunoACT) has received the marketing authorisation approval from the Central Drugs Standard Control Organization (CDSCO), of the first humanised CD19-targeted Chimeric Antigen Receptor T cell (CAR-T cell) therapy product for relapsed / refractory (r/r) B-cell lymphomas and leukemia in India. ImmunoACT is an Indian Institute of Technology (IIT) Bombay incubated company under the aegis of SINE (Society for Innovation and Entrepreneurship) and was founded in 2018.

NexCAR19 is an indigenously developed CD19 targeted CAR-T cell therapy. It is the first-of-its kind, a Made-in-India product and puts the nation firmly on the world map of advanced cell-and-gene therapies.

The multi-center Phase I/ II pivotal clinical trial was conducted with 60 patients of r/r B-cell lymphomas and leukemia. The clinical data indicates ~70% overall response rate (ORR). The safety profile in terms of cytokine release syndrome (CRS) and absence of neurotoxicity indicates a significant improvement over the other commercially approved CD19-directed CAR-T cell therapies.

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 ImmunoACT to scale its R&D and commercialisation efforts.