

October 13, 2023

To  The Corporate Relations Department BSE Limited Phiroz Jeejeebhoy Towers, 25 <sup>th</sup> Floor, Dalal Street Mumbai – 400001  <b>Code: 540222</b>	To  The Listing Department National Stock Exchange of India Limited Exchange Plaza, Bandra Kurla Complex, Bandra (East) Mumbai – 400 051  <b>Code: LAURUSLABS</b>
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Dear Sirs,

Sub: **Disclosure under Regulation 30 - ImmunoACT announces the approval of India's first CAR-T cell therapy, NexCAR19 (Actalycabtagene autoleucel), for the treatment of r/r B-cell lymphomas and leukemia from the Central Drugs Standard Control Organization (CDSCO).**

The Company is pleased to announce that its Associate Company M/s. Immunoadoptive Cell Therapy Private Limited (ImmunoACT) has received the approval of India's first CAR-T cell therapy, NexCAR19 (Actalycabtagene autoleucel), for the treatment of r/r B-cell lymphomas and leukemia from the Central Drugs Standard Control Organization (CDSCO).

A press release issued by ImmunoACT to this extent is also enclosed for your information and records.

Thanking you,

Yours sincerely,  
**For Laurus Labs Limited**

**G. Venkateswar Reddy**  
**Company Secretary &**  
**Compliance Officer**

Encl: As above

**Press Release | Mumbai, October 13<sup>th</sup>, 2023**

**ImmunoACT announces the approval of India's first CAR-T cell therapy, NexCAR19 (Actlycabtagene autoleucel), for the treatment of r/r B-cell lymphomas and leukemia from the Central Drugs Standard Control Organization (CDSCO).**

Immunoadoptive Cell Therapy Private Limited (“ImmunoACT”) received the marketing authorization approval of the first humanized CD19-targeted Chimeric Antigen Receptor T cell (CAR-T cell) therapy product for relapsed / refractory (r/r) B-cell lymphomas and leukemia in India.

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. ImmunoACT's vision is to provide a high quality and affordable CAR-T cell therapy platform to all sections of the society.

The multi-center Phase I/ II pivotal clinical trial, led by Dr Hasmukh Jain, 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. Dr Hasmukh Jain further reiterates, “NexCAR19 has shown an excellent balance of efficacy and low-toxicity, which is a significant advantage in clinical management (post-infusion) of the patients in our resource-constrained settings”.

NexCAR19 is the culmination of a collaborative effort across a decade, between the IIT-Bombay, and Tata Memorial Centre (TMC). Dr Atharva Karulkar, Dr Alka Dwivedi and the team led by Dr Rahul Purwar, Associate Professor at IIT Bombay designed and developed the NexCAR19, which subsequently underwent integrative process development & manufacturing under cGMP at ImmunoACT. Clinical investigations and translational studies were led by Dr Hasmukh Jain and Dr Gaurav Narula and their teams at TMH.

Reflecting on the successful completion of clinical trials, Dr Rahul Purwar, Founder & CEO of ImmunoACT says “This is like a dream come true and an incredible win for the patients in the country. Now our patients in India and countries with limited resources will have access to this life-saving drug at an affordable cost. In terms of technical achievement, this is comparable to the moon shot and it puts India on the elite list of select countries that have access to CAR-T therapy”.

ImmunoACT is an IIT Bombay incubated company under the aegis of SINE (Society for Innovation and Entrepreneurship) and was founded in 2018 with the intention to be able to translate this academic research into a commercially viable product. As per Shirish Arya, Co-founder, and Director – Strategy & Business Development “ImmunoACT is now poised to become the country's leading multi-product, multi-service cell and gene therapy platform that can significantly change the paradigm of healthcare especially in the area of unmet needs”.

Laurus Labs Limited which is a research-driven pharmaceutical and biotechnology company and has a global leadership position in select Active Pharmaceutical Ingredients (APIs) and has been the early backer of ImmunoACT and has invested over USD 18 million to support ImmunoACT to scale its R&D and commercialization efforts. Commenting on this important milestone, Dr Satyanarayana Chava, Founder-CEO of Laurus says “We are very happy and proud to be part of this indigenously developed Cell therapy product for Blood cancer treatment which will help cancer patients in India. This is a fast-evolving technology and we continue to back cutting-edge innovations in the space of cell and gene therapy and new drug discovery”.

Tata Memorial Centre (TMC) Mumbai, is India’s leading centre for cancer research and treatment center and has played a significant role in the Phase I and Phase II pivotal clinical trials. Dr Gaurav Narula, Professor- Pediatric Oncology, and Dr Hasmukh Jain, Professor – Medical Oncology and their team has been the partner for translational studies and clinical studies. Dr Gaurav Narula is the principal investigator (PI) of an investigator-initiated Phase II clinical trial in the pediatric population.

ImmunoACT intends to make the NexCAR19 (Actalycabtagene autoleucel) therapy available to its partner hospitals as soon as possible.

For any further queries, please email at [commercial.operations@immunoact.com](mailto:commercial.operations@immunoact.com)

