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India-Japan Synergies in CAR-T and ADCs

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Cancer remains the leading cause of death globally. As per the World Health Organisation (WHO), there were approximately 9.7 million deaths from cancer in 2022, and around 20 million cancer cases were reported. It is estimated that by 2050, global cancer cases will be around 50 million globally. The rising incidence of cancer has led to a growing focus on individualised and targeted care.

Immunotherapies like CAR-T therapy and antibody-drug conjugates (ADCs) have demonstrated strong clinical efficacy in oncology and continue to be widely adopted within precision medicine practices. The FDA has approved 17 ADCs and 7 CAR-Ts to date. Despite emerging as the most effective therapies for cancer treatment, the broader adoption of CAR-T is hampered by complex manufacturing processes and financial burdens.

The cost of CAR-T globally ranges from $373,000 to $475,000. While Indian CAR-T treatments cost around Rs 30-50 lakh, it is still not accessible to most patients as they are not covered by insurance. Other than affordability, the lack of rural healthcare facilities offering infusion set-ups for CAR-T limits its adoption in India. Thus, there is a need to make CAR-T more accessible.

India ranks second globally in cancer-related mortality and third globally in cancer incidence. As cell and gene therapies (CGTs) can provide improved cancer care, there is a need to establish affordable manufacturing centres for CGTs. Asian nations like Japan and India can capitalise on this opportunity by creating new manufacturing hubs for CGTs. India needs to focus more on developing its own IP to support developments in CAR-T and ADCs and lead the biopharma industry, particularly CAR constructs for Indian cancers (oral, gallbladder, and stomach).

India also needs to focus on innovative technologies like manufacturing cost-effective viral vectors, non-viral delivery methods, smart linker-payload design, AI-driven target discovery, simulated cytotoxicity, and CRISPR-based editing for next-

gen CAR. Growth in the biopharma sector will allow India to emerge as a global innovation hub, save lives, and establish strategic independence in next-generation therapies.

India’s Emergence

NexCAR19, India’s first manufactured CAR-T, was approved in 2023. It was developed by ImmunoACT in collaboration with IIT Bombay and Tata Memorial Centre. NexCAR19 showed a 70 per cent overall response rate, a notable halt in the spread of the cancer, manageable toxicity, and cost around Rs 30-40 lakh, which is one-tenth of the cost of other approved CAR-T therapies.

Cellogen Therapeutics, established in 2021, is developing bi-specific, 3rd and 4th generation CAR T-cell therapies, in line with the latest innovations happening in the field. The CAR-T would be able to target CD19 and CD20 simultaneously, preventing the risk of antigen-escape mediated relapses.

In January 2025, the Central Drugs Standard Control Organisation (CDSCO) authorised Imuneel Therapeutics’ Qartemi, a CD19-targeted CAR T-cell therapy, for adult patients with relapsed or refractory B-cell non-Hodgkin's lymphoma. This approval represents a breakthrough in the country's cancer treatment landscape. This Indian CAR-T is expected to be priced at about $60,000. This would provide an affordable solution to the growing number of cancer patients in India.

Aurigene Oncology is developing India’s first novel autologous BCMA-directed CAR-T cell therapy for patients with relapsed / refractory multiple myeloma. Aurigene's BCMA-targeted CAR-T trial is a major advancement in Indian biotechnology and shows the innovative spirit of the country. In early studies, it was shown that 100 per cent of patients achieved a clinical response and a stringent complete response was achieved in 62.5 per cent of patients. Its Phase 2 approval by the Drugs Controller General of India (DCGI) demonstrates the expanding scientific legitimacy and governmental backing for transforming cancer therapies in India.

Enhancing global reach

India is also making strides in the Antibody-drug Conjugates (ADCs) space with companies like Sun Pharma, Biocon exploring ADC development. With an IND application submitted to the US FDA, Sun Pharma's first ADC, SBO-154, which targets MUC1-SEA in advanced solid tumours, will soon initiate its Phase 1 testing. Biocon is investigating ADCs through international collaborations as well. Although their development stages lag behind those of their international counterparts, which are exploring specific antigens like FR? and CD37, Indian companies' efforts demonstrate their expanding oncology capabilities.

The Contract Development and Manufacturing Organisation (CDMOs) are playing an important role in strengthening India’s position in ADCs landscape. CDMOs like Piramal Life Sciences, Aurigene Pharmaceutical Services, Suven Pharmaceuticals are providing ADCs development and manufacturing services.

Indo-Japan Collaborations

Japan has a comparatively strong ground in the ADC and CAR-T space. Japan’s Daiichi Sankyo's ADC drug, Enhertu, for treating HER2-positive cancers is one of the leading approved ADC drugs. Daiichi Sankyo has a strong ADC pipeline with 7 ADCs in the pipeline and 2 ADC platforms in clinical development. Takeda is also developing CAR-T TAK-007 for multiple myeloma, which is in clinical phase 2 studies. With these active developments, Japan is positioning itself in the global CAR-T and ADCs landscape. There is an opportunity for India to collaborate with Japan through the existing partnership between Japan Science and Technology Agency (JST) and Department of Science and Technology (DST) to take advantage of Japan’s expertise in CAR-T and ADC technologies.

Harmonising Regulatory Policies

At the 6th Asia Partnership Conference on Regenerative Medicine, 2023, both countries discussed regulatory harmonisation in CAR-T cell therapies, with a focus on biodistribution and safety assessment. This is a step towards standardised regulatory frameworks.

In 2024, the 7th India-Japan Medical Product Regulatory Symposium organised by CDSCO and the Pharmaceuticals and Medical Devices Agency (PMDA), continued the regulatory cooperation under the 2015 Memorandum of Cooperation. The symposium was attended by key leaders from the pharmaceutical, medical device, and biologics-biosimilars industries. Discussions focused on the harmonisation of regulations between the two countries. This represents a step forward for promoting developments in CAR-T and ADCs.

The Way Forward

India is gaining attention as an emerging economic developer of CAR-T therapies and a provider of top-level contract development services for ADCs. With approvals of CAR-Ts like Qartemi and NexCAR19 catering to the needs of the Indian population, India is in a strong position to become a prominent global player in the immunotherapy landscape, supported by a solid foundation of startups, clinical trials, and regulatory initiatives.

The partnership between India and Japan will boost innovations and speed up the development in the immunotherapy space and expand healthcare access across Asia. There is a need for more structured India-Japan collaboration, such as co-development research and development partnerships, consortia for translational research, and academia-company partnerships across nations. This collaborative environment will unlock the significant innovation potential in the CAR-T and ADC landscape.

Both nations will benefit by combining their expertise in technological know-how, R&D capabilities and cost-effective development frameworks. India has the potential to transform itself from just an "affordable manufacturer " to a "global innovator".

India needs to engage more actively in commercial and research partnerships with countries making significant progress in this space, such as the US, Europe, and Japan and promote academic-industry-government consortia to accelerate translational research.

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