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Vector BioMed Brings Affordable CAR-T Therapy to Rural India

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Dr. Indraneel Ghosh of Vector BioMed India outlines how the LENTIVERSE™ platform and a nonprofit rural healthcare institution are making advanced therapies accessible to underserved communities

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Dr. Indraneel Ghosh,
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In an exclusive conversation with ***BioSpectrum India*, Ankit Kankar speaks with Dr. Indraneel Ghosh, Country Manager of Vector BioMed India.** Dr. Ghosh shares the vision behind selecting Kailash Cancer Hospital, a nonprofit rural healthcare institution, as the first Indian site for CAR-T deployment. He explains how Vector BioMed's LENTIVERSE™ platform is enabling decentralised and cost-effective manufacturing of advanced therapies, reflects on the philosophy of "democratising cell and gene therapy" championed by founder Dr. Boro Dropulic, and outlines the broader roadmap for expanding access across India's underserved regions.

What were the key considerations in choosing Kailash Cancer Hospital, a rural nonprofit setup, as the first Indian site for CAR-T deployment via Vector BioMed's platform?

Vector BioMed is a public benefit corporation redefining lentiviral vector manufacturing for accessible, affordable gene therapies. Spun out of the nonprofit Caring Cross, the company supports biotech startups, research institutions, and global health systems with customizable and off-the-shelf vector solutions that simplify development and bridge innovation to cure. The philosophy of Vector Biomed as promulgated by the founder Dr. Boro Dropulic is "democratization of cell and gene therapy". Muni Seva Ashram is a very spiritual and peaceful place for peace of mind and health. Muni Seva Ashram was established by Anuben Thakkar in 1980, without any prior mission but only sought to serve the needy and deprived people. At present the main vision of ashram is "To serve, strengthen and sustain the wellbeing of the less fortunate without any discrimination and build organizational resilience through agriculture, health, education, welfare program and alternative energy by deploying most appropriate technologies in total harmony with nature, culture and human values". The principle that 'No service is provided for free, but no one is denied service for the lack of funds' is sincerely followed. Kailash Cancer Hospital and Research Center, under the aegis of Muni Seva Ashram follows the principles of serving without discrimination, aiding without bias, healing without profit, welfare without limitations. These values resonated with Vector Biomed located in Gaithersburg, Maryland. Our senior team members each have decades of experience in Lentiviral vector (LV) and CAR-T cell manufacturing. clinical trial at UPenn; Our current senior team developed the first LV vector used in the production of Kymriah® - first FDA approved CAR-T cell product. Experience with GMP Lentiviral vector production and pre-clinical Lentiviral vector batches bolstered the resolution that cell and gene therapy can be made amenable to everyone including economically disadvantaged groups of patients in LMIC countries. Kailash Cancer Hospital and Research Center caters to those patients afflicted with various types of cancers and are financially not strong

enough to afford treatments like radio therapy, chemotherapy and other modalities. Given the noble mission, Boro Dropulic saw the opportunity to make a difference in the lives of thousands of less fortunate patients. This initial interaction was sheer providence which included my daughter Dhruti and Mr. Deepak Gadhia who played a serendipitous role in initiating the initial interaction.

How does the LENTIVERSE™ platform uniquely enable decentralised, low-cost CAR-T manufacturing and administration, especially in low-resource settings like rural India?

Vector BioMed specializes in providing solutions that empower partners to advance their lentiviral vector-based treatments into clinical trials, thereby expediting their journey to commercialization. In January 2023, Vector BioMed innovated a technological platform for designing and producing lentiviruses utilized in cell and gene therapy LENTIVERSE™ system, is designed for flexibility, affordability, and scalability, especially for low- and middle-income countries (LMICs). Current production systems in India are either manual in bags or using automated systems which are dedicated to one patient cell processing, resulting an average of treating two patients per month. Dedicated systems also have consumables specific to that system which adds to the cost of production. LENTIVERSE™ is a production platform agnostic of expensive consumables or unproductive instrument engagement. In a country where thousands of patients wait for life saving therapeutic cell and gene therapy products, increased processivity with the assurance of no or minimum batch failure due to process generated contamination is of prime importance. LENTIVERSE™ provides the needed processivity of one patient per day with the assurance of safety of the therapeutic product.

In our decentralized model established at Kailash Cancer Hospital and Research Center

Will be able to produce maximum number of therapeutic doses for hematological cancer patients at a significantly less price already available. During CAR-T cell production the outcome of the final therapeutic product depends on the starting cellular material, cellular engineering strategy and ex vivo cell expansion methods. The ensemble of various components of LENTIVERSE™ when implemented results in local on-site production of CAR-T cells at a much lesser cost due to proprietary production techniques and specifically designed components for an accelerated growth without compromising the T cell lineages. The local procurement of process components along with availability of skilled personnel who would produce the actual therapeutic product at much lesser cost as compared to the U.S. allows a faster and way less expensive production cost of CAR-T cells in India using the LENTIVERSE™ system.

Can you elaborate on the regulatory, technical, or infrastructural challenges faced during the evaluation phase—and how they were addressed?

I would use the term novel approaches instead of the word challenge. The esteemed doctors of Kailash Cancer Hospital and Research Center have state of the art facilities like Asias largest day chemotherapy unit, a full-fledged cyclotron, Asias largest solar power parabolic mirror and many more such achievements. The hospital has its own blood bank, pathology lab, 10 operation theaters and pharmacy department, services like Diagnostic imaging, Radiology, CT scan, X-ray departments, Bone marrow transplant unit and Neutropenia care area. Dr.s Yogesh Mistry, Shailesh Lavana, Arpit Patel, Bhavna Chaudhury is the core CAR-T team under the guidance of the director Dr. Vikram Patel. They have a deep understanding of the therapy and the steps required leading to successful conducting of clinical trials. Kailash Cancer Hospital and Research Center is an USFDA approved clinical trial center. The hospital maintains highest standards in every aspect and by no means any less than the so called urban “corporate hospitals”. Late President Dr. Abdul Kalam visited Muni Seva Ashram in 2011 to witness a living example of his life-passion, “Providing Urban amenities in Rural Areas – PURA”.

Given this background it is needless to say that if a cyclotron can be installed and operated a CAR-T facility is relatively much easier proposition to install and operate. Our channel partner Hygine Airtech who has done an excellent job in establishing the GMP facility did the bulk of the work, installation of equipments was supervised by the highly qualified core team of doctors. Their understanding of our process was seamless, and the word challenge was never encountered in the whole process.

What models of affordability are being considered to ensure long-term sustainability of CAR-T therapy delivery at KCHRC, especially beyond initial philanthropic support?

When brilliant minds, across the ocean, of Muni Seva Ashram and Vector Biomed came together an idea nucleated with the sole aim to benefit humanity irrespective of economic capability, religion, race, caste or sex. The model that was decided upon is not dependent on philanthropic aid. Indeed, Philanthropic aid and CSR funding played a pivotal part in initiating the project, however long-term sustenance was also considered in parallel as part of the feasibility studies even before initiating the project. In India medical treatment is mostly covered by private insurance and they do not cover CAR-T cell therapy. The government insurance policy introduced by the Modi government covers 10 lakhs and is not restricted

to certain therapeutic modalities only. Dr. Boro Dropulic decided on offering Kailash Cancer Hospital and Research Center the best possible pricing to enable the cancer afflicted patients to avail this cutting-edge therapy. Dr. Vikram Patel on his side decided to charge only the bare minimum operational cost to the patients. This resulted in pricing which in the major part can be covered by the government Ayushman Bharat policy. For the remaining amount, which is not very large, Muni Seva Ashram is in talks with various insurance companies.

What potential do you see for this collaboration to serve as a template for future CAR-T access points across tier-2 and tier-3 cities in India?

India exhibits wide regional diversity in the incidence, prevalence, and pattern of cancer presentation and care. Nearly 70% of patients suffering from cancer are from rural areas. However almost 95% of the cancer care services are concentrated in urban areas The significant disparity between the demand and supply of cancer care in India can be bridged by following the snowflake model (https://doi.org/10.1200/GO-24-00453).The establishment of CAR-T cell therapy at Kailash Cancer Hospital and Research Center is a case study in itself which goes to show that Dr. Boro Dropulic's dream of democratizing cell and gene therapy is not utopian. During the initiation, progress and completion of the CAR-T cell project at Kailash Cancer Hospital and Research Center, we gathered valuable understanding of the bare minimum requirements of establishing a CAR-T cell therapy project in India which will not treat only affluent patients. Typically, Tier-2 and Tier-3 cities have less resources to establish a full-fledged CAR-T center. Showcasing Kailash Cancer Hospital and Research Center efforts in establishing and treating patients with cutting edge cell and gene therapy utilizing a very economically affordable budget within a reasonable time frame will generate interest of many philanthropic organizations to invest in establishing therapy centers in Tier-1 and Tier-2 cities. We have been approached by many people's representatives to establish centers in their constituencies which mainly comprise of Tier-1 and 2 cities so that people of that constituency do not have to travel long distances for life saving therapies.

How is Vector BioMed planning to work with Indian regulators, policymakers, and academic partners to create an ecosystem for ethical, scalable, and indigenous advanced therapies?

India is the 5th largest global economy, and the fastest growing amongst the G20. India's bioeconomy touched $150 billion this fiscal and we look forward to having $300 billion by 2030, Union Minister Jitendra Singh shared these projections while inaugurating the 3rd edition of Global Bio-India, mega international congregation on biotechnology in New Delhi December 2023. A little more than 1 million new cases of cancer are diagnosed every year in India (~ 8% of the world's cancer patients are in India). Despite a lower incidence of cancer, India suffers a higher mortality rate and without access to advanced interventions, this number is estimated to rise to over 1.3 million by 2040. In India 10,000 to 25000 new cases of CD-19 malignancies (NHL, B-ALL, DLBCL, FL etc) are seen per year out of which 20-45% relapse (2nd I-OSI Annual Conference 2020). Two Pharmaceutical company have obtained commercial license for making CAR-T cells commercially available in India. There is a huge unmet need for treating hematological malignancies and autoimmune disorders. There is no market presence in India of dual and triple CAR-T to treat hematological malignancies and autoimmune disorders. nascent field of treating solid tumors with CAR-T cell therapy. Indian regulators, policymakers, and academic partners are aware of the potential of CAR-T cell therapy and there is no need for creating the ecosystem. Scientists and policy makers from key offices of ICMR, DCGI and CDSCO are familiar with the rule book of approval and commercialization of CAR-T cell therapies. Vector Biomed intends to work closely with them from a very early stage of the program in question. This will generate regulatory authorities' confidence in our product when we apply for permission to conduct clinical trials.