

Bharat Biotech Launches India's Only Vertically Integrated Cell and Gene Therapy, Viral Production Facility at Genome Valley

The company is focused on gene and cell therapies to tackle scientific challenges—such as targeted gene expression, immune system modulation, and long-term cell survival

Hyderabad, India, March 20, 2025: Bharat Biotech International Limited (BBIL), a pioneer in affordable indigenous vaccine development and manufacturing, announced today its foray into Cell & Gene Therapy (CGT) & Viral Vector Production at Genome Valley - expanding its expertise from vaccine innovation to leading-edge regenerative and personalised therapies that promise hope for millions.

This ushers in a new era of gene and cell therapies to tackle scientific challenges—such as targeted gene expression, immune system modulation, and long-term cell survival— The work will span from boosting immune responses against cancer to ensuring that therapeutic proteins are safely accepted in patients with genetic diseases like hemophilia.

The 50,000-square-foot dedicated state-of-the-art CGT facility represents the next milestone in BBIL's longstanding mission to deliver targeted, life-saving treatments that address unmet clinical needs globally by concentrating on critical conditions such as hematological malignancies and inherited blood disorders.

Outlining the purpose behind establishing India's only vertically integrated cell and gene therapy facility, Dr. Krishna Ella, Executive Chairman, Bharat Biotech said, "Gene and cell therapies represent some of the most intricate, scientifically advanced treatments available today, involving sophisticated processes that require expertise in precise genetic manipulation and specialized manufacturing capabilities. Bharat Biotech, with its extensive experience and proven excellence in viral vaccine manufacturing is uniquely positioned to master these complexities and produce human-grade vectors at the scale and consistency needed for clinical trials, thus advancing the global fight against rare and complex diseases."

Dr. Raches Ella, Chief Development Officer, Bharat Biotech, spearheading this CGT initiative, said "Bharat aims to democratize gene therapies, traditionally considered prohibitively expensive and available primarily in developed nations or premium institutions. Our established expertise in producing viral vectors are essential for cell and gene therapy applications - the crucial material for anti-cancer and genetic disorders and robust clinical development abilities for QC release. Additionally, it has capabilities to manufacture multiple platform products for various disease indications, including blood cancers, solid organ cancers, and genetic disorders."

Prof. Krishanu Saha, University of Wisconsin, Madison, said: "Innovations in biomanufacturing for potentially curative cell and gene therapies originate worldwide. It's thrilling to witness the expertise and commitment to developing and scaling novel ideas in India, particularly at Bharat Biotech. My lab has initiated a pioneering collaboration with Bharat Biotech to develop next-generation CAR (chimeric antigen receptor) cell therapies using AI. Ultimately, genuine innovations in both product design and scaling will enhance patient care globally."



"For decades, Bharat Biotech has led India's effort in developing and manufacturing affordable vaccines for critical diseases. "**Cell & Gene Therapy aligns with BBIL's broader vision of expanding beyond traditional vaccines into personalized medicine**. Leveraging our proven expertise in forging strategic global partnerships, this initiative will enable the rapid translation of advanced scientific discoveries—from potent therapeutic vectors to in vivo CAR (chimeric antigen receptor) generation—into real-world solutions." adds **Dr. Krishna Ella**.

Describing the CGT focus Areas to meet the demand for complex disease treatments Dr. Raches Ella added, "Oncology & Rare Diseases treatment therapies are our key focus areas. This facility will support a wide array of advanced therapies, including CD19 CAR T Cell Therapy for Blood cancers and Gene Therapy. Leveraging this deep expertise, Bharat Biotech is not only bridging the gap between scientific innovation and mass affordability but also reaffirming its enduring commitment to democratizing healthcare for the nation and beyond."

Key Differentiators & Technological Innovations

1. **Expert Collaborations**: World-renowned scientific advisory board and global research partners guide us on the latest genome editing and cell manufacturing technologies.

2. Advanced Viral Vector Production: To produce high-titer viral vectors (AAV, Lentivirus, Adenovirus), which are essential for cell and gene therapy applications.

3. **Integrated Quality Assurance**: Specialized teams oversee upstream and downstream processes, ensuring regulatory compliance and delivering viral vectors that meet the highest standards for clinical use.

4. **Scalable Infrastructure**: The purpose is to accommodate continuous expansion as CGT research evolves and demand increases.

Additionally, multiple specialized teams—spanning process development, production, quality assurance, and quality control—will collaborate under one roof to drive the clinical translation of novel therapies. Full-scale operations are on track to commence as the facility finalizes regulatory approvals and completes the remaining build-out phases.

About BHARAT BIOTECH : Bharat Biotech has established an excellent track record of innovation with more than 145 global patents, a wide product portfolio of more than 19 vaccines, 4 biotherapeutics, registrations in more than 125 countries, and the World Health Organization (WHO) Pre-qualifications. Located in Genome Valley in Hyderabad, India, a hub for the global biotech industry, Bharat Biotech has built a world-class vaccine & bio-therapeutics, research & product development, Bio-Safety Level 3 manufacturing, and vaccine supply and distribution. Having delivered more than 9 billion doses of vaccines worldwide, Bharat Biotech continues to lead innovation and has developed vaccines for influenza H1N1, Rotavirus, Japanese Encephalitis (JENVAC®), Rabies, Chikungunya, Zika, Cholera, and the world's first tetanus-toxoid conjugated vaccine for Typhoid.

Bharat's commitment to global social innovation programs and public-private partnerships resulted in introducing path-breaking WHO pre-qualified vaccines BIOPOLIO®, ROTAVAC®, ROTAVAC 5D®, and Typbar TCV® combatting polio, rotavirus, typhoid infections, respectively. HILLCHOL®, an oral vaccine against cholera, was launched in 2024. The acquisition of Chiron Behring Vaccines has positioned Bharat Biotech as the world's largest rabies vaccine manufacturer with Chirorab® and Indirab®. To learn more about Bharat Biotech, visit www.bharatbiotech.com.

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