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Stepping up stem cell research

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Stem cell research stands as a high-priority field in India, as evident by the recent developments. In May 2023, US-based StemCures announced a significant investment of $54 million to establish India's largest stem cell manufacturing laboratory in Hyderabad. Additionally, Stempeutics Research has made significant strides by commercialising India's first allogeneic stem cell therapy, known as Stempeucel, a pioneering treatment designed to rejuvenate blood flow in ischemic tissues, offering hope to patients worldwide. These milestones exemplify India's commitment to advancing stem cells research. Letâ??s explore the advancements in this sector.



The Indian government is bullish on the stem cell sector. The Department of Biotechnology (DBT) has been actively involved in supporting projects spanning various aspects of stem cell research, including basic biology, translational research, gene editing technology development for potential therapies, and the creation of animal models for human diseases. The DBT allocated funds totaling Rs 7,345.58 lakh during the period from 2019 to 2022.

There have been a flurry of activities in this space in recent times. The introduction of Stempeutics Research's Stempeucel in partnership with Cipla in 2020 marked a groundbreaking achievement in India's stem cell sector. It secured the distinction of being the first allogeneic cell therapy product approved for commercial use in India and globally, as the world's inaugural stem cell product for the treatment of Critical Limb Ischemia (CLI) due to Buerger's Disease and Atherosclerotic Peripheral Arterial Disease.

Stempeucel, which took over 12 years to develop, represents a revolutionary therapy designed to augment the body's innate ability to restore blood flow in ischemic tissue. Currently, the firm is planning to enter other international markets, including the US, EU, and Japan.

In 2022, Stempeutics in collaboration with Alkem Laboratories, launched the first 'made-in-India' off-the-shelf cell therapy product known as 'StemOne' to treat Knee Osteoarthritis (OA). It is the first approved allogeneic cell therapy product for commercial use in India to address knee OA. The firm is also evaluating stem cell therapy for diabetic foot ulcers and in May 2023, announced the completion of patient enrollment for this critical phase 3 study.

"While the United States, the European Union, and China currently lead in preclinical mesenchymal stem cell research, India has achieved a significant milestone with the approval of its stem cell product, Stempeucel. In contrast, both the USA and China have yet to obtain approval for any stem cell products. Stempeucel obtained approval for two specific conditions, poor circulation and knee pain resulting from osteoarthritis, and is derived from the culture expansion of bone marrow mesenchymal stem cells. With this precedent established, it is anticipated that this development will serve as a catalyst for future advancements in stem cell therapies. This holds significant promise for India, as it possesses immense potential in addressing various medical conditions that presently lack effective treatment options," said **Dr Sairam Atluri, Founder, StemCures USA**.

In May 2023, StemCures announced its intention to invest $54 million in establishing India's largest stem cell laboratory in Telangana.

In August 2022, Bengaluru-based cell therapy company Eyestem successfully raised $6.4 million in Series A funding. They are currently developing EyeCyte-RPE, an experimental treatment intended for Dry Age-related Macular Degeneration (Dry AMD).

In September 2023, Eyestem submitted an Investigational New Drug (IND) application to the Central Drugs Standards Control Organization (CDSCO), paving the way for the commencement of first-in-human trials for Eyecyte-RPE.

Research institutes in the country have played a crucial role in understanding the molecular-level intricacies of stem cells. This understanding has been pivotal in identifying the underlying causes of diseases, thus paving the way for the development of improved treatment approaches.

To that effect, on September 6, 2023, SKAN Research Trust (SKAN) partnered with the Wellcome-MRC Cambridge Stem Cell Institute (CSCI) from the University of Cambridge to bring cutting-edge stem cell research to India. This collaboration aims to advance disease prevention, diagnosis, and treatment through targeted stem cell research projects in the field of regenerative medicine.

In August 2023, researchers at IIT-G (Indian Institute of Technology Guwahati) developed a method to transform regular human skin cells into iPSCs (Induced pluripotent stem cells), which can be programmed into different adult cell types, offering significant potential for treating diseases like diabetes, cancer, paralysis, and Alzheimer's. This approach bypasses the traditional extraction of stem cells from embryos or specific body parts, addressing ethical and practical concerns. Using a safe, integration-free method, the team introduced genes into skin cells, making them iPSCs, which maintained their genetic integrity and versatility for differentiation into various body cell types.

Speaking about other developments in this space, **Dr Subadra Dravida, Founder, Transcell Biologics**, said, "Hematopoietic stem cell transplantations on cell therapy model becoming the first line of treatment in curing blood cancers; The regenerative medicinal value of stem cells in repair and regeneration addressing defects to manage diseases like osteoarthritis, autism, muscular dystrophies are the latest developments. The breakthrough innovation where India can become global leader is in the field of applying stem cell technology integrated into the digital revolution to offer safety efficacy testing as a solution to the global pharma and biopharma industries replacing animal testing and outdated contract testing strategies."

Hyderabad-based Transcell Biologics, a knowledge driven technology investing entity has evolved from its inception as an R&D unit to a fully integrated biotechnology enterprise encompassing a well balanced business portfolio offering indigenous technologies on biobanking, in vitro products for drug discovery research, intellectual property in regenerative medicine/Immunotherapy for clinical practice.

A long road to accessibility

Experts are bullish on stem cells' future in the country, with exciting developments in store.

"The breakthrough innovation of integrating stem cell technology with digital revolution on Artificial Intelligence (AI) and Machine Learning (ML) tools is the next big thing, breaking grounds, unravelling the stem cell tech potential becoming application reality. The strength of this digital animal free testing strategy that leverages stem cell tech and AI/ML tools is for every pharma and biopharma player adding value in their discovery, development and manufacturing for real time applications speaking on the affordability as well as accessibility to the end user," said Dr Dravida.

Stem cells, often regarded as miraculous for treating genetic disorders, remain beyond the reach of many patients in need. These cells hold the potential to cure numerous diseases. The cost of stem cell transplant therapy ranges from Rs 5-8 lakh, depending on the specific disease being treated, according to PayBima report.

Experts believe that additional investments are necessary within the field of stem cell research. While the current situation is promising, it calls for increased funding to establish India as a prominent player in stem cell research.

"Given that these stem cells are considered 'living' drugs, it is imperative to exercise meticulous attention during the manufacturing process to ensure both potency and safety. The manufacturing facility must adhere to both current Good Manufacturing Practices (cGMP) and regulatory guidelines. Clinical trials are essential to establish the safety and efficacy of these therapies, albeit they may result in increased costs. However, India's advantage lies in its access to a comparatively less expensive yet highly knowledgeable labour pool, which can help mitigate some of these challenges. Presently, India appears to be a fertile ground for innovations in various fields, including medicine. It is conceivable that over the next decade, mesenchymal stem cell therapy will gain momentum and widespread acceptance. While the high cost associated with this therapy may pose challenges in terms of patient access, India has demonstrated its capability to overcome such challenges, as evidenced by its successful 'Chandrayaan' mission. This suggests that India has the potential to address and find solutions for the affordability and accessibility issues related to advanced medical treatments like mesenchymal stem cell therapy," said Dr Atluri.

The stem cells field is often plagued with controversy both globally and in India. In December 2022, the Navi Mumbai Municipal Corporation (NMMC) revoked NeuroGen Brain and Spine Institute's licence for providing stem cell therapy (SCT) to children with autism. Stem cell therapy is still experimental for autism, lacking enough data for definitive claims. The Ethics and Medical Registration Board (EMRB) recommended against its use due to potential risks, adverse reactions, and limited

understanding of long-term effects. However, in September 2023, the Delhi High Court granted permission for two children diagnosed with autism spectrum disorder (ASD) to continue their stem cell treatment, emphasising that abruptly stopping the treatment may not be in the best interest of the patients.

Stem cell research is a highly promising field, especially in regenerative medicine. It presents innovative ways to treat various diseases and conditions. Moving forward, ethical, regulatory, and accessibility considerations will be crucial in shaping this sector.

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