TechSci Research
from NOW to NEXT

TechSciGoesPink

Regenerative Medicine Market

TechSci Research Analysts in Conversation with:

Prashant Kshatriya

(Head and Senior Scientist at Viecell Institute of Regenerative Medicine)

Can you briefly describe your journey and what led you to specialize in regenerative medicine?

My master's degree was finished in 2013. Following the results, I received a job offer in Mumbai that was somewhat related to my field of expertise, but I wasn't particularly interested in it. My goal was to work in the clinical field, so I read scientific magazines and occasionally found research articles about novel and alternative approaches to medicine.

One day, I came across an article about the regeneration of beta cells, which are destroyed in type 1 diabetes. This piqued my interest and motivated me to read more about regenerative medicine. However, because it was my first job, I accepted the offer, even though it felt like a robot coming to work every day and performing the same tasks without using any mind. I then began looking for work in this industry, and after a year of struggle, I was hired as a junior scientist by a small business. I did, however, acquire knowledge of various departments, including regulatory, article writing, research proposal writing, and—most importantly—differing cell culture techniques—because it was a small company with a small number of scientific staff members.

I have now worked in this field for more than ten years, having had number of research articles published in various journals. I am currently in charge of the cell therapy research at the Viecell Institute of Regnerative Medicine in Surat, Gujarat.

What specific areas of regenerative medicine are you most focused on currently?

At present, I am engaged in a variety of cell therapy projects. However, I am more interested in tissue regeneration with exosomes and mesenchymal stem cells.

How has regenerative medicine evolved in recent years, and where do you see it heading in the next 5-10 years?

Regenerative medicine is emerging as a major force in the medical field after decades of research. Though there are still many challenges to be

Prashant Kshatriya

Head and Senior Scientist at Viecell Institute of Regenerative Medicine

solved, the potential of regenerative medicine is expanding with every experiment. Regenerative medicine has had a significant impact on tissue repair and transplantology, despite this. The rapidly expanding interdisciplinary field of regenerative medicine, which involves stimulating and promoting the regeneration of damaged or diseased tissue, holds great promise for improving our understanding of cellular processes and enabling customized treatments for a variety of ailments.

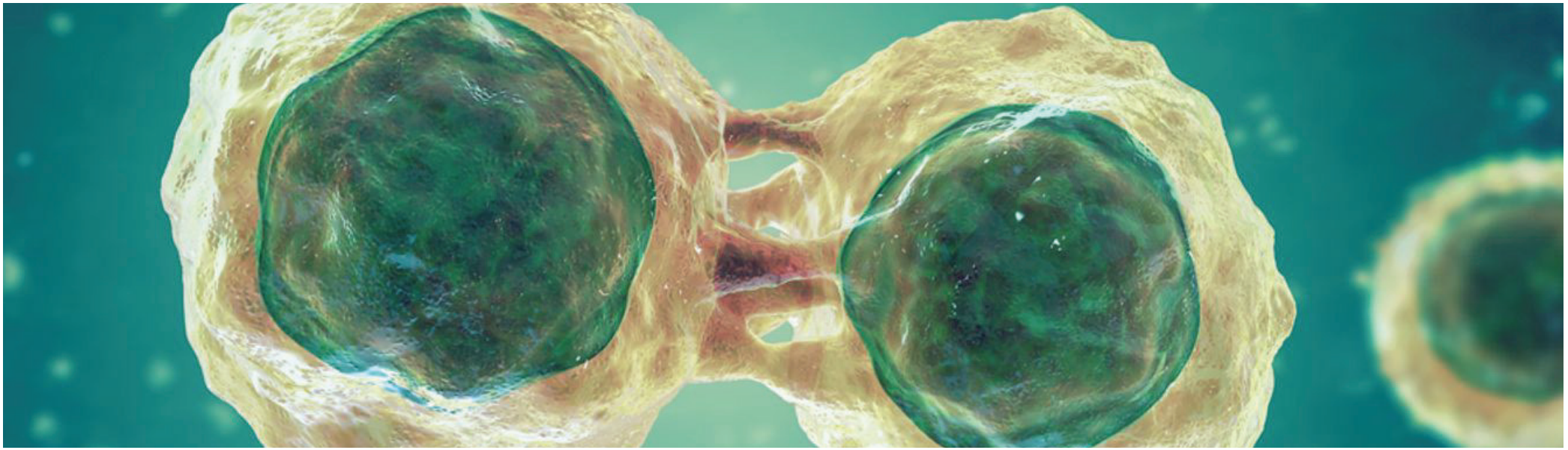
As the field has developed, the state-of-the-art in these treatments has shifted from using tissue grafts to replace lost tissue to introducing growth factors to promote the body's natural healing process to using more recent materials like stem cells, which have the capacity to differentiate into a vast array of different cell types. Thus, stem cells offer a perfect medium for tissue generation and have greatly sparked interest in the field.

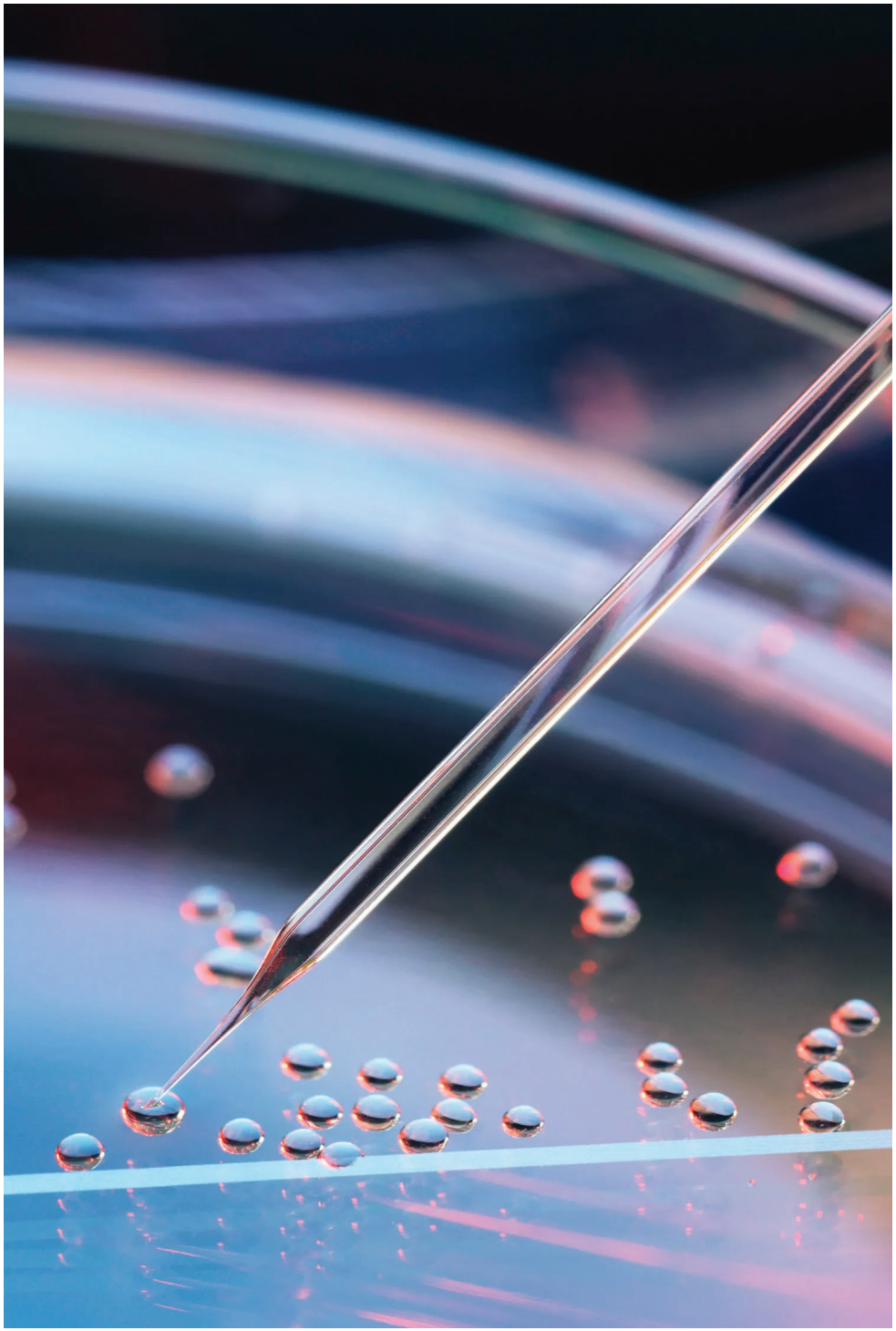
What do you believe are the most promising areas of regenerative medicine (e.g., stem cell therapy, tissue engineering, gene therapy, or biologics)?

All of these, in my opinion, are related. Biologics use the proteins and growth factors secreted by cells in therapeutics that increase cell-cell communications. Stem cells are live, intact cells that can be transplanted into patients to treat disease. Tissue engineering uses cells, biomaterials, and scaffolds to repair and restore damaged tissues. Gene therapy involves transferring genetic material, usually in the form of a carrier or vector, and the gene is absorbed into the appropriate cells of the body.

What have been the most significant breakthroughs in the field in your opinion?

A noteworthy development in recent times pertains to the application of CRISPR gene-editing technology to specifically target genetic disorders that are linked to chronic pain conditions. Furthermore, significant advancements have been made in the field of tissue engineering





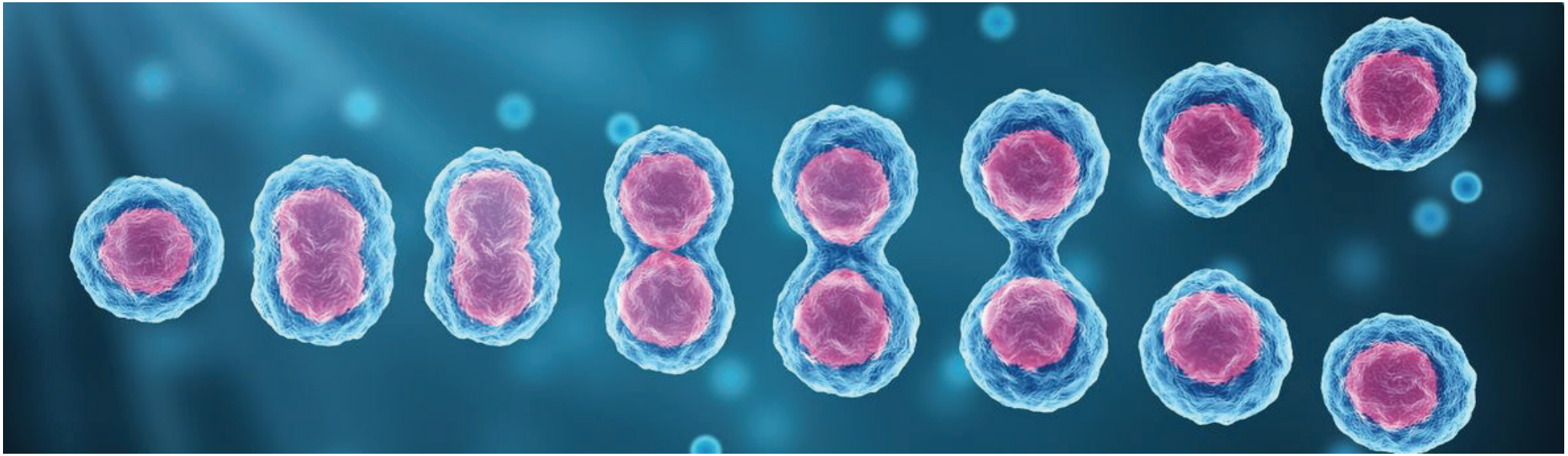
toward the development of lab-grown tissues that can integrate with the human body to replace or repair damaged organs. A pioneering achievement in liver research has been the transplantation of lab-grown liver tissues into animal models, where the tissues not only survived but also started to function normally.

This accomplishment gives hope to the millions of patients waiting for organ transplants around the world and represents a major advancement in organ transplantation and regeneration.

How do you see the role of AI and technology influencing regenerative medicine research and treatments?

- Artificial intelligence (AI) has the potential to expedite the advancement of regenerative therapies by streamlining processes like examining extensive molecular and genetic data datasets and spotting patterns and correlations that human researchers might overlook. This can aid in the development of more potent treatments to address the underlying disease mechanisms and a better understanding of them by researchers.

- AI's capacity to assist in determining which cells are optimal for a given patient is one of the main advantages of using it in cell therapy. Artificial intelligence algorithms are able to forecast which cells will most likely be useful in treating a patient's condition by examining their genetic information and medical history. AI can also assist researchers in determining the best environments for cell growth. One crucial step in cell therapy that can have a big impact on the treatment's outcome is getting the cells to the target site. By streamlining the administration process and guaranteeing that the cells arrive at the intended location, artificial intelligence (AI) can enhance the delivery of cells. In order to optimize therapeutic benefits, AI can also assist in determining the ideal dose and timing of cell delivery. It can also help with cell tracking post-delivery, tracking migration and survival, and identifying any negative effects. This



may help modify the treatment strategy and enhance patient results. The application of AI in cell therapy has certain restrictions in addition to its possible advantages. A primary constraint is the caliber and volume of accessible data. For AI algorithms to forecast results with accuracy, vast volumes of high-quality data are needed. However, patient data in the field of cell therapy are frequently sparse and varied, which makes it difficult to effectively train AI models.

What current regenerative medicine therapies do you think show the most promise in clinical applications?

At the moment, exosomes and stem cell therapy are showing encouraging results in the treatment of degenerative diseases in their early stages.

Can you share your thoughts on how regenerative medicine can address some of the most challenging conditions, such as neurodegenerative diseases or cardiac failure?

- Currently, stem cell therapy presents a bright future for nearly all neurodegenerative illnesses, such as Parkinson's disease (PD), Alzheimer's disease (ADLD), amyotrophic lateral sclerosis (ALS), and Huntington's disease (HD). Progressive loss of neuronal number, structure, or function, including neuronal death, is the basic mechanism underlying all forms of neurodegenerative diseases.

  The various types of neurodegenerative diseases share many similarities at the molecular level. Unfortunately, none of the current therapeutic options—pharmacological or neurosurgical—are effective in stopping the advancement of neurodegenerative processes. Conversely, stem cell therapy promotes neural tissue regeneration, which lessens neurodegeneration that affects the neuronal circuitry at various levels.

- One of the main causes of death globally is cardiovascular disease, or CVD. Researchers have currently proposed numerous strategies for the prevention and treatment of CVD; the most promising of these are therapies based on stem cells. It has been reported that stem cell transplantation procedures, such as intravenous, epicardial, cardiac, and endocardial injections, significantly improve clinical outcomes. Nevertheless, a number of issues, including the type and quantity of transplanted cells and post-transplantation health, still require investigation and consideration.

How do you approach integrating regenerative therapies into current medical treatments?

Since research on bone marrow transplants has increased our understanding of stem cell therapy, regenerative medicine has gained recognition as an emerging field of medicine. Regenerative medicine can complement current medical treatments based on the patient's condition.

For instance, early-stage hip replacement can be avoided by utilizing bone marrow aspiration and concentration for avascular necrosis of the femoral head in conjunction with surgical core decompression, which has improved patient outcomes.

What are the key challenges facing regenerative medicine research today (e.g., regulatory, ethical, technical)?

- Standardization: Because these treatments and technologies are intricate and quickly developing, creating standards for regenerative medicine is difficult. Furthermore, stakeholders must reach a consensus on standards, which can be challenging to achieve.

- Regulation: The field of regenerative medicine encounters regulatory obstacles such as navigating a multifaceted regulatory

framework and being uncertain about the most suitable regulatory pathway for specific emerging technologies and therapies.

- Manufacturing: Manufacturing is the process of creating goods from raw materials in a way that is largely repeatable and consistent. The cells, tissues, and organs used in regenerative medicine are complex and challenging to produce on a large scale, but it is an essential first step for many new technologies and treatments. A lack of infrastructure and problems guaranteeing consistency and quality are two more issues facing the manufacturing industry.

How do you address the issues surrounding immune rejection in stem cell or tissue transplantation?

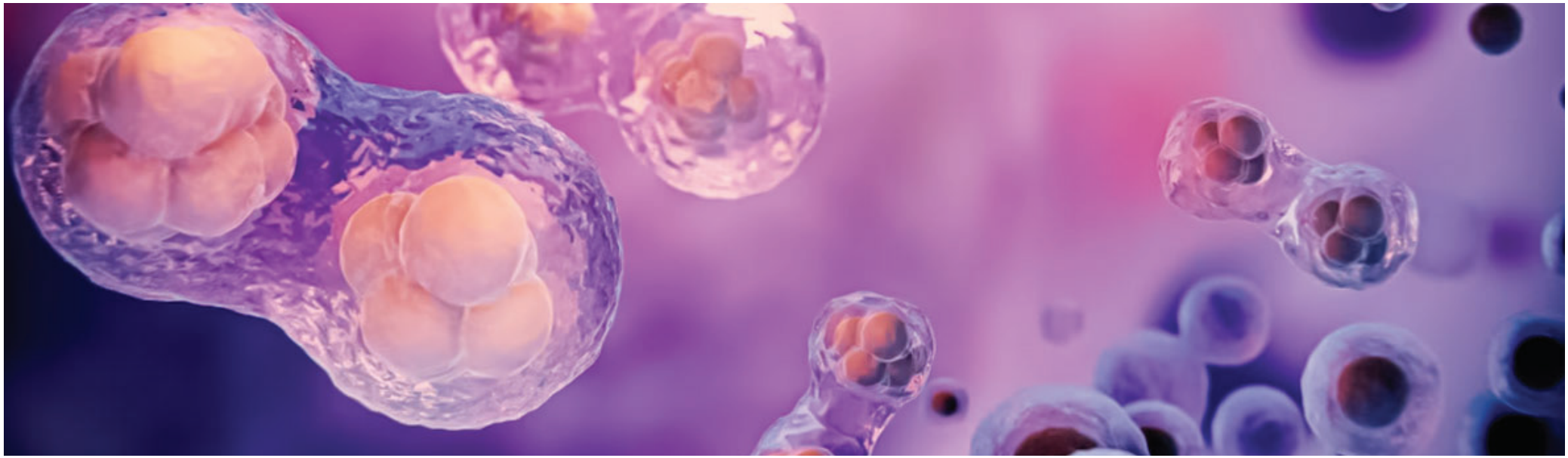
Immune rejection can be mostly avoided with stem cell or tissue transplantation based on HLA matching. Even so, a low-immunity rejection substitute that is straightforward and stable is required. In order to lower the possibility of unintended clinical hazards, this alternate strategy should refrain from making significant changes during commercialization, such as refraining from employing viral vectors or gene editing.

What do you see as the biggest barriers to widespread adoption of regenerative medicine technologies in healthcare?

High Cost, not having single window for regulatory approvals, uncertainty in the treatment results.

How do you think regulatory agencies (e.g., FDA, EMA) are handling approvals for regenerative therapies? Is the process too slow, or are there reasons for the caution?

Regenerative therapies are subject to a changing regulatory environment. In order to expedite the approval of regenerative medicine, regulators have taken proactive measures. It is still difficult to address the differences in regulatory requirements across international borders.



What role do you see for pharmaceutical companies and biotech startups in driving the future of regenerative medicine?

The future appears promising. Companies in the biotech and pharmaceutical sectors are now at the forefront of therapy and the treatment of various diseases. Effective treatments and drug development have benefited greatly from advances in molecular science, new technologies, R&D, novel ideas, and manufacturing process optimization. For instance, Cipla owned a business called stempeutics, which has introduced several approved stem cell products both domestically and internationally.

How can regenerative medicine companies improve their strategies for commercialization, scaling, and patient access?

- Fast And Flexible Manufacturing And Supply Chain: In order to meet production targets, companies will need to find engineers and other qualified technicians who can recognize and use the technologies required. It will also be necessary for them to schedule intensive, possibly temporary adjustments to their production capacity early in the life cycle of the product.

- More Precise Patient Targeting: Companies will need to assist clinicians in quickly screening and identifying suitable patients at every stage, from clinical development to commercialization, in order to enable commercial success. It will be necessary to have accurate, consistent, and widespread biomarkers as well as associated diagnostics.

- Collaborating With The Right Stakeholders: These days, a lot of producers of gene and cell therapies are also reaching out to interdisciplinary stakeholders, such as clinicians, patients, patient advocacy groups, and healthcare providers (HCPs), who can offer crucial viewpoints and demands regarding commercial strategies and market adoption. They rely on patient advocates to develop

accurate evaluations of the advantages and disadvantages of various drug delivery strategies. In certain situations, they also evaluate treatment protocols and dosing options, as well as certain concerns about distribution, the location of treatment facilities, and longer-term patient monitoring. Insights from stakeholders can also influence market access subsequent to product launch and aid in pricing decisions.

- Seeking New Opportunities For Growth: Identifying and pursuing growth opportunities is crucial for companies developing gene and cell therapies, as it increases the likelihood of their commercial success. Experts generally concur that these drug developers should concentrate their initial commercial efforts on the U.S. s. Recognizing that this strategy will rely on the worldwide prevalence of a target disease, and EU before expanding to other geographical areas once they establish best practices. Gene and cell therapy companies, however, may also occasionally target less developed markets where new curative therapies can be quickly positioned as standard of care without first taking incremental improvements in treatment or symptom management into account.

In your opinion, what are the top considerations for investors looking to support regenerative medicine technologies?

- Challenges are Data, Regulations and Security

- Despite many obstacles, there are plenty of opportunities in the regenerative medicine sector. The possibility of company collaboration and partnerships is one of these. Many regenerative medicine businesses are tiny start-ups that might lack the funding or know-how to create treatments independently. Through partnerships with larger pharmaceutical companies or other businesses, these start-ups can

expedite the development of novel therapies and expedite their introduction to the market.What do you believe is the role of governments and policymakers in shaping the future of regenerative medicine?

- Increasing Collaboration Among Stakeholders
- Defining the Role of Patient Advocates in Shaping Regulatory Policy
- Biorepositories and Data Sharing
- Unregulated Therapies and Medical Tourism

With many therapies still in development, how do you see the balance between innovation and ethical responsibility?

Research on stem cells holds significant potential for comprehending fundamental mechanisms of human development and differentiation. Additionally, it may lead to novel treatments for ailments like diabetes, myocardial infarction, Parkinson's disease, and spinal cord injury. However, there are also significant political and ethical issues surrounding human stem cell (hSC) research.

To make sure that stem cell research is conducted in an ethically acceptable manner, these ethical and policy concerns need to be discussed in addition to the scientific difficulties.

Where do you see the potential for "personalized regenerative medicine" and the use of patient-specific therapies?

- Personalized medicine, which focuses on tailored therapeutic approaches based on patient-specific characteristics, is still relatively new. However, population-based approaches still account for the majority of treatments. So, personalized medicine has not only increased life quality and access to healthcare, but it has also decreased the cost of ineffective treatments, assisting government

agencies dealing with health-related issues in managing health care costs. Lowering the risks and adverse effects of conventional medications while optimizing the therapeutic potential of health interventions and establishing the highest quality treatment approaches are the objectives of personalized medicine. Powerful tools for genetic profiling of various cancer types have been implemented as a result of significant advancements in personalized medicine, an innovative medical approach. Considered a fundamental element of personalized medicine, molecular diagnostics aid in the development of response prediction and appropriate treatment determination, facilitating the monitoring of therapeutic effect efficacy on a broad range of diseases.

- The most promising approach to improving the quality of medical services through customized care is personalized medicine, which can provide insight into how patients are treated based on their unique characteristics.

Can you discuss the importance of clinical trials in validating regenerative medicine therapies?

- The treatment is novel and has not yet undergone human testing. Novel therapies must go through rigorous testing in humans during development to guarantee their safety and effectiveness.

- The treatment has been authorized to address a particular medical condition in patients who fit a particular demographic; for instance, participants in the early stages of a novel drug's trial who have the target medical condition and are between the ages of 18 and 65 are frequently the subjects of these trials. In order to determine whether it is suitable for use in other groups, more clinical trials must be carried out by researchers.

- Researchers are looking into whether the treatment can be helpful in

other circumstances or for other disorders, even though it has been approved for a particular purpose or disorder.

- The treatment has been approved, and researchers are investigating a new method for administering the treatment.

What do you think is the biggest challenge in designing effective clinical trials for regenerative treatments?

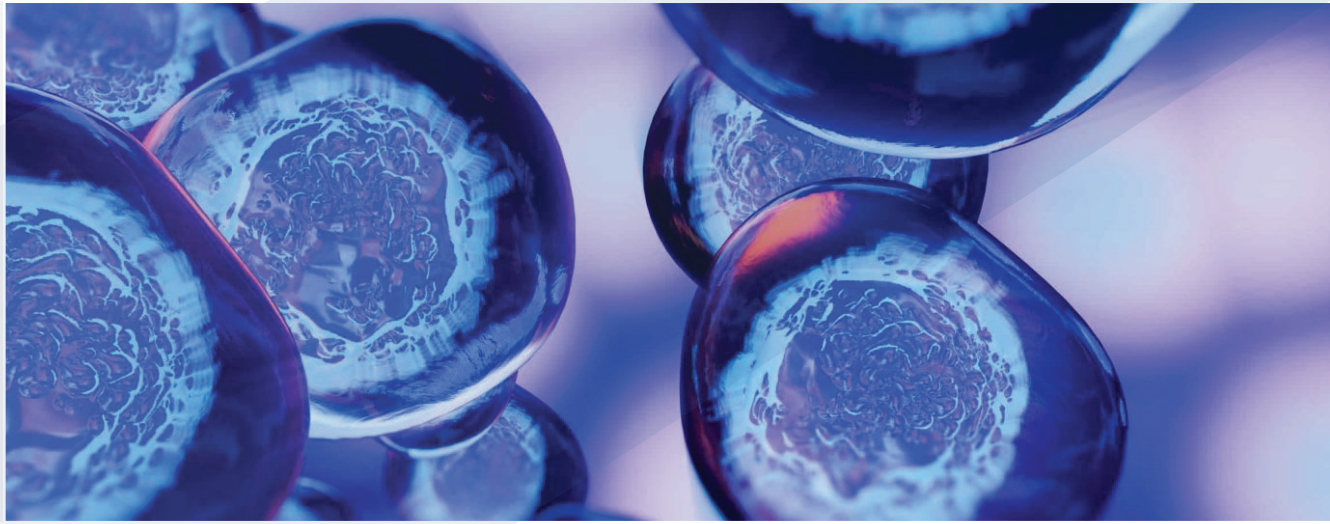
- Both clinical-academic and commercial models are essential to the innovation process due to the high costs associated with developing and producing these treatments, and the scientific and clinical complexity of these treatments as well as the uncertainties surrounding their development make clinical-academic input crucial. These two models reflect opposing views of the ideal future for cell therapies in addition to being complementary aspects of innovation.

- The growing involvement of major pharmaceutical companies in stem cell therapies is a clear sign of their confidence in the field [43]. Profound funding from institutions like the California Institute for Regenerative Medicine and their global collaborators is probably going to propel the growth of new clinical trials in the coming years.

Are there specific biomarkers or diagnostics that you believe are critical in advancing the field of regenerative medicine?

Regenerative medicine is still in the process of developing biomarkers that can distinguish patients who are likely to respond to stem cell therapy from those who are not, sparing them the risk, suffering, and inconvenience of an unnecessary invasive intervention, based on the expression of a clinical or molecular profile congruent with the therapeutic mechanism-of-action (MOA) of the stem cell for that condition. In the end, this kind of patient stratification will be necessary to guarantee safety, effectiveness, and sensible resource distribution.

TechSci Research
from NOW to NEXT



ABOUT TECHSCI HEALTHCARE

TechSci Healthcare vertical offers market research & consulting services in the healthcare industry with a major focus on pharmaceuticals, medical devices, consumer healthcare, animal healthcare, biotechnology, and healthcare IT domains. TechSci Research also focuses on providing market intelligence on emerging technologies and niche industries that have the potential to cause a high level of disruption in the market in the next few years. We excel in conducting market viability analysis for technologies that are still in the nascent stages of their lifecycle.

AUTHORS

Karan Chechi

Research Director

Shaurya Singh

Senior Research Analyst

Manvi Suri

Junior Research Analyst