

December 16, 2024  
Japan Tissue Engineering Co., Ltd.

To Meet the Need for Alternatives to Animal Testing in India  
**J-TEC and Shiven Biotech Sign a Distributor Agreement  
Concerning the Sale of Cultured Human Tissue for Research Use**

Japan Tissue Engineering Co., Ltd. (J-TEC, headquarters in Gamagori, Aichi Prefecture; President and CEO: Ken-ichiro Hata) and Shiven Biotech (headquarters in Maharashtra, India; CEO: Pranav Desai) signed a non-exclusive distributor agreement on December 16, 2024, concerning the sale of cultured human tissue for research use "LabCyte" in India to be used as an alternative to animal testing in the development of medical and cosmetic products. With a global movement going on to end animal testing from the perspective of animal welfare, J-TEC aims to increase the sale of "LabCyte" rapidly in India where enormous market growth is expected, meeting the need for alternatives to animal testing.

## 1. Background

- (1) In the development of medical and cosmetic products, animal testing has been conducted to check the impact of the ingredients in the product on humans. In recent years, however, there have been accelerating moves around the world to use animal testing alternatives from the perspective of animal welfare, as seen in the EU where animal testing in cosmetics development was totally banned in 2013.
- (2) With the growth of its economy, India has seen the demand rise for the development of medical and cosmetic products. In 2014, on the other hand, the country banned animal testing in cosmetics development as well as the import of cosmetic products developed through animal testing. Its market for animal testing alternatives is expected to grow even further. The size of this market, which stood at approx. 2.55 billion yen in 2020, is forecast to roughly double to approx. 4.67 billion yen by 2025\*1 and keep growing at high rates after that.
- (3) J-TEC brought to market Autologous Cultured Epidermis "JACE," which was Japan's first regenerative medical product. A pioneer in the field of regenerative medicine, the company has been committed to the commercialization and social implementation of regenerative medicine. Since 2005, J-TEC has marketed cultured human tissue for research use "LabCyte" created by applying the advanced cell culture techniques that it has nurtured in the development of regenerative medical products. With "LabCyte," artificial tissues made by culturing human skin or corneal cells are substituted for laboratory animals.
- (4) Established in 2014 and headquartered in Maharashtra, the financial capital of India, Shiven Biotech is a biotech supplier of research materials among other products. The company procures products from major US, UK, and EU manufacturers in the life science industry and distributes those products in India. It has a track record of doing business with research institutes, universities, and corporations that may be prospective users of "LabCyte."
- (5) Under these circumstances, J-TEC was considering the Indian market as the next key target for its overseas expansion along with Europe and the US. To ensure that "LabCyte," a living cell-based product whose effective period is short, is delivered quickly to customers, we have decided to sign a non-exclusive distributor agreement with Shiven Biotech that boasts a track record of importing and marketing multinational biotech products in India.

\*1 Source: MARKETSANDMARKETS "IN VITRO TOXICITY TESTING MARKET GLOBAL FORECAST TO 2025"

## 2. About this agreement

- (1) J-TEC will sell "LabCyte" to contract research organizations, cosmetics development firms, and universities in India through the distribution channels that Shiven Biotech has in the country.
- (2) The two companies will collaborate in sales promotion activities such as visits to Indian customers and presentations at academic conferences.

## 3. About cultured human tissue for research use "LabCyte"

- (1) "LabCyte" is a suite of artificial tissue models produced by culturing human cells in vitro and reconstructing tissues so that they are similar to human tissues in structure and morphology. There are two varieties of "LabCyte." "EPI-MODEL" mimics the human skin, and "CORNEA-MODEL" mimics the cornea. These models can be used in tests conducted to check the impact of cosmetic and medical products on the skin or cornea.
- (2) "LabCyte" not only eliminates the need to use laboratory animals but, since its structure is very similar to that of human tissues, it enables more accurate verification of the impact on humans. As we perform all the processes internally, from manufacturing to selling, allowing us to deliver products in a short time and maintain a stable product supply under thorough quality control.
- (3) Spurred by strong demand for alternatives to animal testing, sales have grown by roughly 2.5 times over the last 10 years, and we have the largest share of the Japanese market.



LabCyte EPI-MODEL (Reconstructed Human Epidermis)

### [Comment from Ken-ichiro Hata, President and CEO, J-TEC]



The "LabCyte" series is high-quality cultured human tissues for research use developed by applying our manufacturing technology of regenerative medical products. In Japan, these tissues are already used by many customers and recognized as an appropriate animal testing alternative. We intend to take advantage of the distributor agreement with Shiven Biotech to provide our products smoothly to India where strong growth is expected to continue. Keep your eyes on us as we promote "LabCyte" further on a global scale.

### [Comment from Pranav Desai, CEO, Shiven Biotech]



We at Shiven Biotech are honored and excited about this partnership with J-TEC. Given the recent increase in In-Vitro toxicological testing studies in India and its vast potential of growth in future, it will be our endeavor that J-TEC will be benchmark in supplying the RHE tissue models to the Indian customers. Along with the technical and product support we will surely develop new customers and testimonials for "LabCyte" in Indian market.

#### 4. Future outlook

- (1) In expanding the sales of "LabCyte," Shiven Biotech will be focused on acquiring new customers in India and boost its sales capability.
- (2) Building on the expansion into India, J-TEC will seek to increase the share of "LabCyte" in overseas markets and to expand the "LabCyte" business, one of the pillars of its growth strategy. Furthermore, by increasing sales in India, J-TEC will proceed with the expansion into other overseas regions as well.
- (3) J-TEC will keep aiming to achieve its vision "Creating a Future for Regenerative Medicine" by fully utilizing the techniques it has nurtured as a pioneer in the field of regenerative medicine of Japan.

#### (Reference: About J-TEC)

J-TEC is a maker of regenerative medical products. Our vision is "Creating a Future for Regenerative Medicine", and we have been a member of the Teijin Group since March 2021. As the top runner in Japan's regenerative medicine industry, we provide a stable supply of regenerative medical products, and of the regenerative medical products that have been approved in Japan, the following five are J-TEC products.

- ✓ Approved Oct. 2007: Autologous Cultured Epidermis JACE®  
– Japan's first regenerative medical product
- ✓ Approved July 2012: Autologous Cultured Cartilage JACC®  
– Japan's first regenerative medical product in the orthopedics field
- ✓ Approved March 2020: Autologous Cultured Corneal Epithelium NEPIC®  
– Japan's first regenerative medical product in the ophthalmology field
- ✓ Approved June 2021: Autologous Cultured Oral Mucosal Epithelium OCURAL®  
– The world's first regenerative medical product using oral mucosal epithelial cells
- ✓ Approved March 2023: Autologous Cultured Epidermis Maintaining Melanocytes JACEMIN.  
– Second regenerative medical product in Japan in the skin field

Please visit [www.jpte.co.jp/en/](http://www.jpte.co.jp/en/)

#### (Reference: About Shiven Biotech)

Shiven Biotech was established in the year 2014 to serve the Life Science Industry in India. Innovative products from leading manufacturers of life science industry based in US, UK and European countries. Shiven Biotech mission is to provide the most comprehensive product range in the fields of biotechnology, molecular biology, genomics, proteomics, pharmaceuticals sciences etc. for the international and national Life Science R&D communities.

Please visit <https://shivenbiotech.com/>

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