

J-TEC Acquires Rights to a Patent for Human Intestinal Epithelial Models Using iPS Cell-Derived Organoids from Takara Bio

Japan Tissue Engineering Co., Ltd. (Headquarters: Gamagori, Aichi; President: Kenichiro Hata; hereinafter "J-TEC") has signed an agreement to acquire the rights to a patent from Takara Bio Inc. (Headquarters: Kusatsu, Shiga; President: Koichi Nakao; hereinafter "Takara Bio") for the commercialization of a human intestinal epithelial model. This model is developed using organoids cultured from human iPS cells and will be added to J-TEC's "LabCyte" series, a lineup of human cultured tissue models used as alternatives to animal testing in pharmaceutical and cosmetic development.

1. Background and Rationale

(1) Shift Away from Animal Testing in Drug and Cosmetic Development

In pharmaceutical and cosmetic development, animal testing has traditionally been conducted before clinical trials on humans to predict the effects of drugs. However, in recent years, concerns over the limitations of animal models in accurately reflecting human responses have accelerated global research and adoption of alternative testing methods. Additionally, from an animal welfare perspective, regulations prohibiting animal testing in cosmetic development have been established in regions such as the U.S. and Europe.

 $(2)\;$ J-TEC's Efforts in Alternative Testing Models

Recognizing this trend, J-TEC has leveraged regenerative medicine technologies to develop the "LabCyte" series—human cultured tissue models derived from human skin and corneal cells to evaluate the effects of substances on human tissues. Since launching in 2005, the series has maintained the largest market share in Japan for animal testing alternatives. Moreover, in 2024, J-TEC signed a distribution agreement with India's Siven Biotech, expanding its presence in international markets.

(3) Demand for Intestinal Epithelial Models in Drug Development

Looking ahead, J-TEC anticipates increasing demand for alternatives to animal testing not only in cosmetics but also in pharmaceutical development, particularly for intestinal epithelial models. Intestinal absorption and metabolism studies are critical processes in the development of orally administered drugs. However, existing models, such as those using cancer cell lines or intestinal epithelial-like cells derived directly from human iPS cells, present challenges in terms of accuracy and stable production.

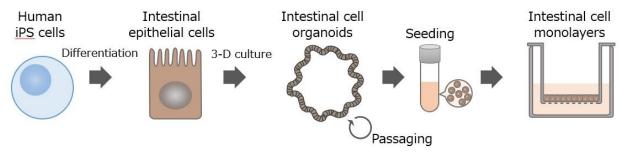
(4) Agreement with Takara Bio for Advanced Organoid Technology

To address these challenges, J-TEC has reached an agreement with Takara Bio to acquire rights to a patented technology for manufacturing research-use intestinal epithelial models utilizing human iPS cell-derived intestinal organoids. This technology offers superior accuracy and stability, paving the way for more reliable testing models in drug development.

2. Overview of the Acquired Technology

(1) Intellectual Property Transfer from Takara Bio

Under this agreement, J-TEC will acquire ownership and exclusive usage rights from Takara Bio for multiple patents related to the differentiation of human iPS cells into intestinal epithelial cells and the organoid technology for stable production of intestinal epithelial models. This technology was co-developed by the visiting project leader at the National Institutes of Biomedical Innovation, Health and Nutrition, Professor Hiroyuki Mizuguchi of the Graduate School of Pharmaceutical Sciences at Osaka University and Takara Bio.



Process of creating an intestinal epithelial model using human iPS cells and organoid technology

- (2) Advancements in Research-Use Intestinal Epithelial Models
 - Building on this technology, J-TEC will develop a new research-use intestinal epithelial model. By inducing optimal differentiation of human iPS cells, this model will replicate intestinal epithelial cells with functions closely resembling those of the human small intestine, meeting the stringent data accuracy requirements of pharmaceutical development. Additionally, stable organoid cultivation will ensure long-term cell viability, enhancing manufacturing efficiency and enabling the production of high-quality, consistent products with rapid delivery times ultimately maximizing customer satisfaction.

3. Future Outlook

(1) Product Launch and Market Expansion

J-TEC aims to launch the new intestinal epithelial model in the first quarter of the 2026 fiscal year. With this product, the company plans to expand its focus beyond cosmetics into the pharmaceutical sector, while also accelerating its global expansion in the U.S., Europe, and Asia, targeting early revenue growth in the scale of several billion yen.

- (2) Broader Applications of iPS and Organoid Technologies Through the development and manufacturing of this product, J-TEC will deepen its expertise in iPS cell and organoid technologies. This will not only enhance its existing portfolio of single-cell-based products but also enable the expansion of microphysiological systems (MPS) product lineups. Moreover, J-TEC will explore the development of innovative multi-organ models and next-generation regenerative medical products, further advancing alternatives to animal testing.
- (3) Commitment to Regenerative Medicine Innovation As a pioneer in regenerative medicine in Japan, J-TEC remains committed to leveraging its cutting-edge technologies to address unmet medical needs worldwide. The company continues to strive towards its vision of creating a future for regenerative medicine.

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