

January 14, 2025
Japan Tissue Engineering Co., Ltd.

Japan Tissue Engineering and VCCT Inc. Form a Capital and Business Alliance to Put iPS Cell-Based Regenerative Medical Products to Practical Use

Japan Tissue Engineering Co., Ltd. (J-TEC, headquarters in Gamagori, Aichi Prefecture; President and CEO: Ken-ichiro Hata) and VCCT Inc. (VCCT, headquarters in Kobe, Hyogo Prefecture; President: Masayo Takahashi) signed an agreement on a capital and business alliance on December 27, 2024, to accelerate efforts to put to practical use an iPS cell-based regenerative medical product for retinal degenerative diseases (development name: MastCT-03), which VCCT is developing by using a new technology expected to improve effectiveness and safety.

J-TEC has commercialized five regenerative medical products, the most among Japanese medical product manufacturers. VCCT, led by Masayo Takahashi, carried out a clinical application involving iPS cells for the first time in the world. These two companies will collaborate to realize the practical use of an iPS cell-based regenerative medical product for retinal degenerative diseases for which no curative therapy exists.

1. Background

- (1) iPS cells, short for induced pluripotent stem cells, are created by culturing human skin or blood cells. Since they have the ability to differentiate into many different cell types, iPS cells are increasingly used in such applications as the development of regenerative medical products and new drugs.
- (2) To commercialize an iPS cell-based product and expanding its use requires overcoming a host of challenges, including securing research and development funds, establishing manufacturing processes implementing quality control systems, and developing distribution networks, in addition to creating superior product concepts and advanced development technologies.
- (3) VCCT is a RIKEN-certified venture company established in 2021 to work on the commercial use of ophthalmology-related regenerative medical products. Building on the clinical experience and track record of Masayo Takahashi, an ophthalmologist, the company is developing a regenerative medical product that can provide curative therapy for currently incurable retinal degenerative diseases, in partnership with Kobe City Eye Hospital.
- (4) In 2007, J-TEC brought to market Autologous Cultured Epidermis "JACE," the first regenerative medical product to be marketed in Japan. As a pioneer in the regenerative medicine field committed to the industrialization and social implementation of regenerative medicine, the company has so far commercialized five regenerative medical products, the most among Japanese medical product manufacturers.
- (5) J-TEC and Masayo Takahashi have been engaged in a joint development effort since 2009 to develop iPS cell-derived retinal cells for the treatment of retinal diseases. In 2014, a team primarily composed of members of RIKEN's R&D project on retinal regenerative medicine led by Masayo Takahashi succeeded in the transplantation of iPS cell-derived RPE cell* sheets to a patient with exudative age-related macular degeneration for the first time in the world.
- (6) Given these circumstances, we determined that combining VCCT's advanced iPS cell technology with J-TEC's experience and expertise in product commercialization, production, and sales in Japan would accelerate the practical implementation of MastCT-03. Furthermore, J-TEC's support in post-marketing quality control and establishment of production and sales systems will enable faster delivery of the product to patients suffering from retinal degenerative diseases. These factors led to the formation of this capital and business alliance.

* RPE cell: Retinal pigment epithelial cell in the retina. As aging, stress, or some other factor produces degenerative changes in these cells, symptoms such as poor vision develop.

2. About this alliance

- (1) J-TEC will provide support in drug preparation and regulator handling, including the creation of a cell bank that provides source cells for MastCT-03 and the development of containers that maintain the quality of test products, thus assisting VCCT in obtaining domestic marketing approval. It is also agreed that, when the domestic production and sales of MastCT-03 is outsourced as it is brought to market, VCCT will give preferential negotiating rights to J-TEC for a certain period of time.
- (2) Based on this alliance agreement, J-TEC will offer funds to VCCT, which will in turn further drive its efforts to develop and commercialize ophthalmology-related regenerative medical products by using these funds.

3. About the iPS cell-based product being developed by VCCT (development name: MastCT-03)

- (1) MastCT-03 is genome-edited iPS cell-derived RPE cells targeted at retinal degenerative diseases. Retinal degenerative diseases are known to be a major cause of blindness in Japan and other developed nations. They include age-related macular degeneration that develops as aging\some other factor causes atrophy in the central retina, leading to low vision, as well as retinitis pigmentosa that causes total retinal degeneration due to gene mutations. Age-related macular degeneration in particular is the most common cause of visual impairment worldwide and the fourth common cause in Japan. While an extremely large number of patients are suffering from this disease, there is no established curative therapy for the degenerated retina. The treatment of this disease represents a significant unmet medical need.
- (2) The iPS cells that are the source of MastCT-03 are cells taken from another person. To make these iPS cells less prone to post-transplantation immunorejection, the molecules responsible for such rejection are removed from the cells.
- (3) With MastCT-03, RPE cells created from iPS cells are aggregated into thin strip (RPE cell aggregation strings). This ensures that the cells are implanted in the appropriate location beneath the retina using a syringe, facilitating surgical procedures and hence reducing the burden on the patient. Moreover, after being implanted beneath the retina, the strip -shaped clumps of cells are expected to produce the best effect as they spread in sheet form. Using these two epoch-making technologies in combination improves the safety and effectiveness of MastCT-03, making it a possible curative therapy for retinal degeneration.

Figure 1: Implantation of MastCT-03

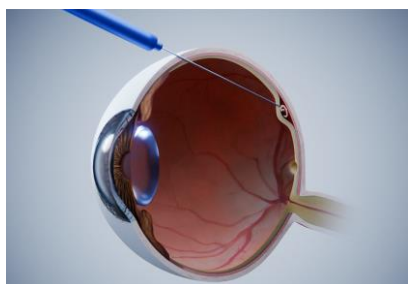


Figure 2: RPE strip of MastCT-03



Future outlook

- (1) J-TEC will aim to expand iPS cell-related entrusted business on a long-term basis. Also, building on our track record as a pioneer in Japan's regenerative medicine, we are going to support the commercialization of selected excellent technologies of corporations and academic organizations at home and abroad, thus contributing to the growth of the regenerative medicine industry.
- (2) VCCT will focus on completing its two main therapies: retinal pigment epithelial cell transplantation and photoreceptor cell transplantation. The company will develop not only cell-based products but also medical care approaches including treatment methods and social systems with the goal of offering cures as soon as possible to many patients who could become visually impaired because of the lack of effective treatment.

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



I have long known Dr. Takahashi partly because of my relationship with NIDEK CO., LTD., our former parent company that founded J-TEC. The iPS cell technology, developed in Japan, is phenomenally expanding a range of possibilities of regenerative medicine. Dr. Takahashi is a pioneer in iPS cell-based clinical applications, who has been devoted not just to high-level basic research but to the development of products for clinical use as well. We share the same vision, which has led J-TEC to decide to offer funds and form an alliance. Taking full advantage of the experience in the social implementation of regenerative medicine that we have promoted over the years, we will work together with Dr. Takahashi to make as many patients happy as possible.

[Comment from Masayo Takahashi, President and Representative Director, VCCT]



J-TEC cooperated with us when we conducted the first-ever clinical application of iPS cell-derived retinal pigment epithelial cell transplantation.. In the following 10 years, we have continued to improve dosage forms and treatment methods, making it the best possible treatment. Now, we are about to start preparations for a clinical trial necessary to deliver this treatment to many patients. We have confidence in the technology we have developed, and I believe that the cooperation of J-TEC, which its extensive experience in putting regenerative medical products into general use, will enhance the reliability of our treatment. I am profoundly grateful to J-TEC for offering us a remarkable level of reliability and a comprehensive support.

(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

(Reference: About VC Cell Therapy Inc.)

VCCT Inc. (RIKEN-certified venture) was established in March 2021 as a subsidiary of Vision Care Inc. The company conducts R&D activities in ophthalmology and regenerative medicine to research and develop regenerative medical technologies, produce and market regenerative medical products, and acquire, possess, license, transfer, and manage relevant intellectual properties, with the aim of quickly realizing the practical use of regenerative medicine. In June 2024, VCCT established VCCT USA inc. in the state of California, USA, to prepare for clinical trials there.

[Contact information for inquiries about this announcement]

Japan Tissue Engineering Co., Ltd. E-mail. jtec-info@jpte.co.jp