June 11, 2021
Japan Tissue Engineering Co., Ltd.

Marketing approval obtained for Autologous Cultured Oral Mucosal Epithelium “Ocural” — World’s first regenerative medical product using oral mucosal epithelial cells for the treatment of limbal stem cell deficiency —

Japan Tissue Engineering Co., Ltd. (“J-TEC”, headquarters in Gamagori, Aichi, Japan; President & CEO Ken-ichiro Hata) is pleased to announce that marketing approval was obtained for Autologous Cultured Oral Mucosal Epithelium “Ocural” on June 11, 2021.

“Ocural” is a product for the treatment of limbal stem cell deficiency,[*1] and it is the world’s first regenerative medical product using oral mucosal epithelial cells to treat this disease. This product will be manufactured in Japan and was developed through the practical application of technology developed by Prof. Kohji Nishida of the Department of Ophthalmology, Osaka University Graduate School of Medicine. It will be Japan’s second regenerative medical product in the ophthalmology field, following Autologous Cultured Corneal Epithelium “Nepic”,[*2] for which marketing approval was obtained in March 2020.

“Ocural”, the product for which marketing approval was obtained this time, is a sheet of epithelial cells derived from human (autologous) oral mucosa that is manufactured by harvesting the patient’s own oral mucosal tissue and culturing the cells isolated from it. The purpose of the product is to repair damaged corneal epithelium, and when this product is transplanted onto the surface of the patient’s eyes, the patient’s own oral mucosal epithelial cells become engrafted and epithelialize. “Ocural” is a promising new treatment method for patients who have extensive damage to the cornea of both eyes from limbal stem cell deficiency and have markedly reduced visual acuity. “Ocural” was designated a regenerative medical product for the treatment of rare diseases[*3] in 2020, with the indication of limbal stem cell deficiency.

As the top runner in regenerative medicine in Japan, J-TEC obtained marketing approval for Autologous Cultured Epidermis “JACE”, which became Japan’s first regenerative medical product, in 2007, and began marketing it in 2009. J-TEC went on to obtain marketing approval for Autologous Cultured Cartilage “JACC” in 2013 and Autologous Cultured Corneal Epithelium “Nepic” in March of 2020. “JACC” and “Nepic” were Japan’s first regenerative medical products in the orthopedic surgery and ophthalmology fields, respectively.

Through the practical application of “Ocural” in addition to “Nepic”, J-TEC has made it possible to provide therapies for corneal epithelial diseases, for which curative treatment methods previously did not exist. J-Tec is promoting the industrialization of regenerative medicine and contributing to the improvement of patients’ quality of life (QOL) by further strengthening sales of its existing products and accelerating the development of new regenerative medical products.

1. Summary

The following is a summary of the marketing approval.

Approval number	30300FZX00003000
Approval date	June 11, 2021
Nonproprietary name	Human (Autologous) Oral Mucosal Epithelial Cell Sheet
Brand name	Ocural
Indications, effects, or performance	Limbal stem cell deficiency
Approval conditions	1. The MAF must take the necessary measures, such as widely disseminating proper use guidelines prepared in cooperation with the related learned societies and providing training to physicians, to ensure that this product is used only by physicians (a) who have sufficient knowledge of and experience with limbal stem cell deficiency, (b) have acquired a sufficient knowledge of the skills involved in the method of use, and of the potential complications associated with use of the procedure, and (c) will use the product in compliance with the "Indications, effects, or performance" and "Dosage and administration of method of use", at a medical institution that is equipped to handle the treatment of limbic stem cell deficiency. 2. Because the number of clinical trial cases is extremely limited, the MAF should, as a general rule, strive to grasp background information on the patients using this product and collect data on the safety and efficacy of this product early on by conducting surveys of the results of use in all cases, and also take the necessary measures to ensure proper use of this product, until the end of the reexamination period. 3. In light of the risks associated with heterologous transplantation of the 3T3-J2 cells derived from mouse embryos that are used as feeder cells in the manufacturing process for this product, the MAF must take the necessary measures to ensure proper handling, such as retaining samples of the final products and records related to use for 30 years.

2. History

In the development of this product, an investigator-initiated clinical trial was conducted by Prof. Kohji Nishida and Lecturer Yoshinori Oie et al of Osaka University Graduate School of Medicine (Department of Ophthalmology) with support from AMED.[*4] J-TEC introduced the autologous cultured oral mucosal epithelial cell sheet transplantation technology that Dr. Kohji Nishida led the world in developing, and took over the investigator-initiated clinical trial, conducting it as a corporate-sponsored clinical trial of "Ocural" since September of 2016. In September of 2020, J-TEC submitted a marketing approval application to the Ministry of Health, Labour and Welfare for "Ocural" as the second regenerative medical product in the ophthalmology field. "Ocural" is to be marketed by ophthalmological medical device maker Nidek Co., Ltd. (Gamagori, Aichi; President and CEO Motoki Ozawa).

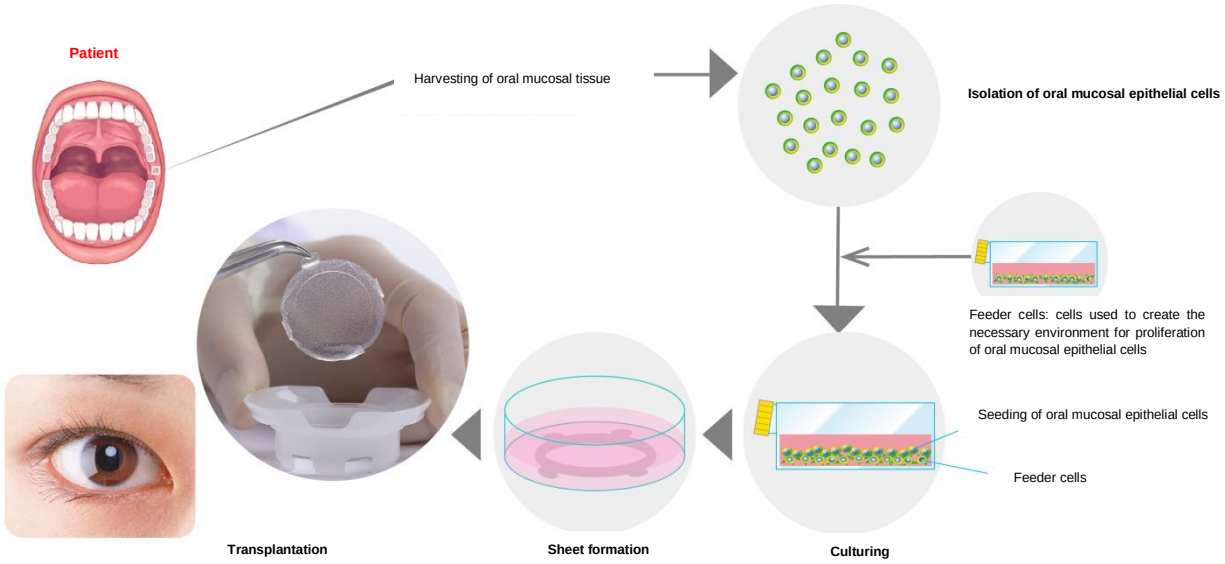
*1 A disease in which corneal epithelial stem cells, which exist in the corneal limbus at the border between the cornea and the conjunctiva, are lost owing to congenital or exogenous factors. LSCD presents with clinical symptoms such as clouding of the cornea, decline in visual acuity, and eye pain.

*2 Regenerative medical products for the treatment of orphan diseases that are designated by the Minister of Health, Labour and Welfare in accordance with the Pharmaceuticals and Medical Devices Law. Products with this designation receive preferential treatment, such as grants for research, priority clinical trial consultation and review, and extension of the reexamination period. In order for a product to be designated a regenerative medical product for orphan diseases, it must have a target disease that affects fewer than 50,000 patients in Japan and lacks a suitable alternative treatment method, and the product must have exceptional medical utility value, such as efficacy and safety that can be expected to greatly surpass those of existing treatment methods.

*3 NEPIC is made by culturing corneal epithelial stem cells harvested from the patient's own corneal limbic tissue into the form of sheets that are transplanted back into the patient's eyes to reconstruct the corneal epithelium. NEPIC was included in the National Health Insurance price list in June of 2020, and it is marketed by Nidec Co., Ltd.

*4 Japan Agency for Medical Research and Development

Transplantation of autologous cultured oral mucosal epithelium “Ocural”



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