May 24, 2021
Japan Tissue Engineering Co., Ltd.

Reviewed and acknowledged by MHLW subcommittee: approval of autologous cultured oral mucosal epithelial cell sheet (development code: COMET01)

Japan Tissue Engineering Co., Ltd. (J-TEC; headquarters in Gamagori City, Aichi Prefecture; President & CEO, Ken-ichiro Hata) is pleased to announce that marketing approval of our autologous cultured oral mucosal epithelial cell sheet (Development Name: COMET01) for the treatment of limbal stem cell deficiency (LSCD) [*1] has been reviewed and acknowledged at today's meeting of the Regenerative Medical Products and Biological Technology Subcommittee of the Ministry of Health, Labour and Welfare's Pharmaceutical Affairs and Food Sanitation Council.

COMET01 is epithelial cell sheet derived from human (autologous) oral mucosa. It is prepared by harvesting oral mucosal tissue from the patient and then cultivating the isolated cells. The purpose of this product is to repair defective corneal epithelium by transplanting the sheet onto the ocular surface, where the patient's own oral mucosal epithelial cells become engrafted and epithelialize. COMET01 is a promising new treatment method for patients who have extensive damage to the cornea of both eyes and markedly reduced visual acuity owing to LSCD.

COMET01 was designated a regenerative medical product for orphan diseases [*2] — specifically the treatment of LSCD — in 2020.

J-TEC introduced the transplantation technique for autologous cultured oral mucosal epithelial cell sheets developed by Professor Kohji Nishida of Graduate School of Medicine/Faculty of Medicine, Osaka University (Department of Neural and Sensory Organ Surgery (Department of Ophthalmology)) and has taken over the investigator-initiated trial conducted by Professor Nishida's group, conducting it in the form of a company-sponsored clinical trial of COMET01 since September of 2016. In September of 2020, J-TEC submitted an application for marketing approval of COMET01 to the Ministry of Health, Labour and Welfare as Japan's second regenerative medical product in the ophthalmology field.

Marketing of COMET01 is to be conducted by Nidek Co., Ltd. (Gamagori City, Aichi Prefecture; President and CEO, Motoki Ozawa), a maker of ophthalmology and optometry products.

As the top runner in regenerative medicine in Japan, J-TEC obtained marketing approval for autologous cultured epidermis "JACE", Japan's first regenerative medical product, in 2007 and began marketing JACE in 2009. Marketing approval was then obtained for autologous cultured cartilage "JACC" in 2013 and for autologous cultured corneal epithelium "NEPIC" [*3] in March of 2020. JACC was Japan's first regenerative medical product in the orthopedic surgery field, and NEPIC was the first in the ophthalmology field.

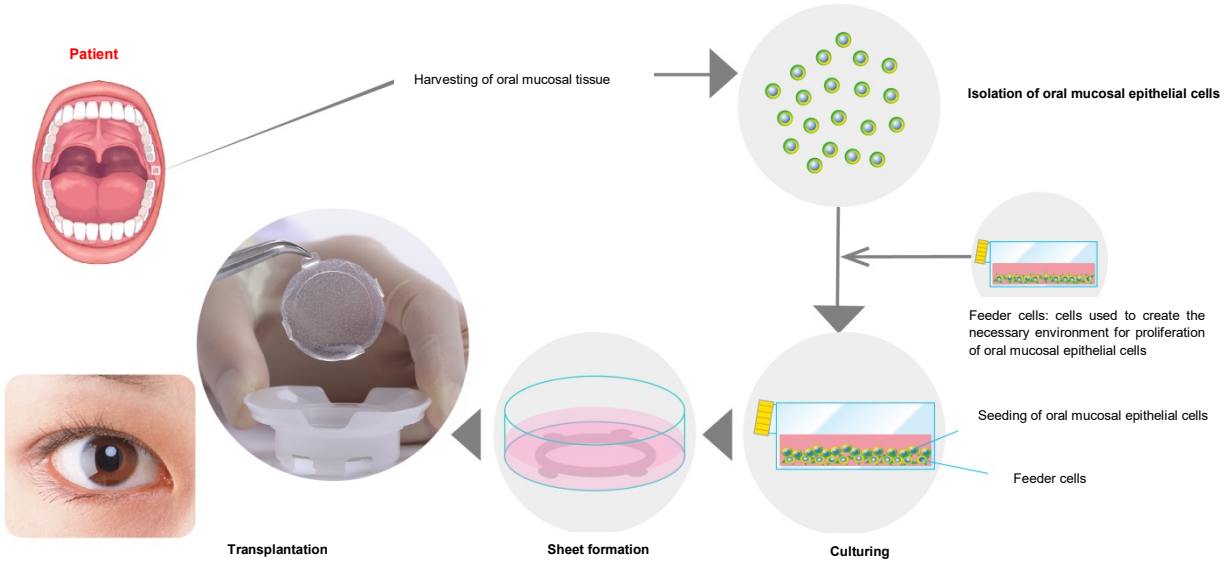
Through the practical application of first NEPIC and then COMET01, J-TEC has succeeded in providing a treatment method for corneal epithelial diseases for which no curative therapy previously existed. By reinforcing sales of existing products and accelerating development of new regenerative medical products, J-TEC is promoting the development of regenerative medicine into an industry while also contributing to the improvement of patients' quality of life (QOL).

*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.

Transplantation of autologous cultured oral mucosal epithelium (Development Name: COMET01)



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