

**Towards the Creation of Novel Regenerative Medical Products in the Field of Ophthalmology
Marketing Approval Application for Autologous Cultured Oral Mucosal Epithelium
(Development Name: COMET01)**

September 14, 2020

Japan Tissue Engineering Co., Ltd.

The Fujifilm subsidiary Japan Tissue Engineering Co., Ltd. (J-TEC, head office: Gamagori City, Aichi Prefecture, President & CEO: Kenichiro HATA) has announced that it has made a marketing approval application to the Ministry of Health, Labour and Welfare for autologous cultured oral mucosal epithelium (development name: COMET01), a regenerative medical product for the treatment of corneal epithelial stem cell deficiency^{*1}.

J-TEC has introduced techniques for autologous cultivated oral mucosal epithelial cell sheet transplantation developed by Professor Koji NISHIDA of Osaka University Graduate School of Medicine (Department of Ophthalmology) and performed a sponsor-initiated clinical trial of COMET01 since September 2016 following an investigator-initiated clinical trial performed by Professor Nishida's group.

COMET01 is a cell sheet derived from autologous oral mucosal epithelium prepared by cultivating cells collected and isolated from patients' own oral mucosal tissue. It is transplanted to enable the regeneration and proliferation of the patient's own oral mucosal epithelial cells and reconstruction of missing corneal epithelium. COMET01 is anticipated as a new treatment for patients with extensive corneal opacity in both eyes and markedly reduced visual function due to corneal epithelial stem cell deficiency.

COMET01 is to be marketed by the ophthalmological medical device manufacturer NIDEK Co., Ltd. (Gamagori City, Aichi Prefecture, President and CEO: Motoki OZAWA).

As a pioneer in regenerative medicine in Japan, J-TEC obtained marketing approval for the first regenerative medical product in Japan, the autologous cultured epidermis "JACE," in 2007 and began marketing in 2009. With the aim of promoting the spread of regenerative medicine, the autologous cultured cartilage "JACC" came on the market in 2013 and the autologous cultured corneal epithelium "NEPIC^{*2}" was introduced in 2020. JACC and NEPIC were the first regenerative medical products in Japan in the fields of orthopedic surgery and ophthalmology, respectively.

By further consolidating sales of its existing products and accelerating the development of new regenerative medical products, J-TEC will continue to promote the commercialization of regenerative medicine and contribute to improving quality of life (QOL).

^{*1} A disease that occurs due to the disappearance of corneal epithelial stem cells present in the corneal limbus, the boundary region between the conjunctiva and the cornea, as a result of congenital or external factors. Clinical symptoms such as corneal opacity, reduced visual acuity, and ophthalmalgia are observed.

^{*2} NEPIC is marketed by the ophthalmological medical device manufacturer NIDEK Co., Ltd.



Autologous cultured oral mucosal epithelium
(Development name: COMET01)