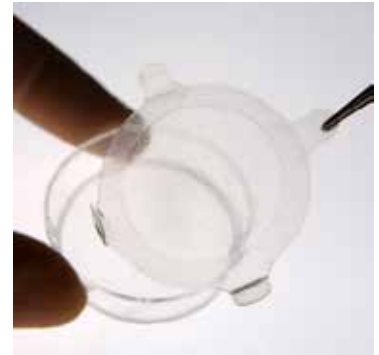


**Announcement of Application for Manufacturing and Marketing Approval for Cultured Autologous Corneal Epithelium (Development name: EYE-01M)****- First application for a regenerative medical product in the field of ophthalmology in Japan -**March 20, 2019  
Japan Tissue Engineering Co., Ltd.

Fujifilm subsidiary Japan Tissue Engineering Co., Ltd. (J-TEC; head office in Gamagori, Aichi Prefecture; President: Kenichiro Hata) has filed an application with the Ministry of Health, Labour and Welfare for manufacturing and marketing approval of cultured autologous corneal epithelium (development name: EYE-01M) for the treatment of corneal epithelial stem cell deficiency\*.

This application, made for a custom development project commissioned by ophthalmic medical device maker Nidek Co., Ltd. (Gamagori, Aichi Prefecture, President: Motoki Ozawa), is the first application for marketing approval for a regenerative medical product in the ophthalmology field in Japan.



EYE-01M

“EYE-01M” is cultured in sheets after corneal epithelial cells are harvested from the limbus of the patient’s own corneal tissue and is then transplanted back to the patient in order to reconstruct the corneal epithelium and thereby improve visual acuity and other clinical symptoms (eye pain, feeling of a foreign body, lacrimation, feeling of dryness, etc.).

Under commission to develop “EYE-01M” by Nidek, J-TEC introduced technology for culturing corneal cells from Professor Graziella Pellegrini and Professor Michele De Luca of the University of Modena and Reggio Emilia in Italy and from Professor Koji Nishida (Ophthalmology) of Graduate School of Medicine/Faculty of Medicine, Osaka University, and has been conducting a clinical trial since October 2014.

J-TEC is presently drawing upon the knowhow that it accumulated and the systems it established in the development of Japan’s first regenerative medical product, autologous cultured epidermis “JACE”, to pour its energies into the custom development and manufacturing business for regenerative medicine. The goal is to provide one-stop and seamless support, not only the development of its own products, but also for Contract Development and Manufacturing Organization (CDMO) projects that develop investigational products and engage in commercial production, as well as Contract Research Organization (CRO) projects that engage in pharmaceutical consulting and conduct clinical trials, from the earliest phase of regenerative medical product development through to the post-marketing stage. The application for manufacturing and marketing approval for “EYE-01M” is part of a contract development project commissioned from Nidek. According to the contract, marketing of “EYE-01M” will be performed by Nidek.

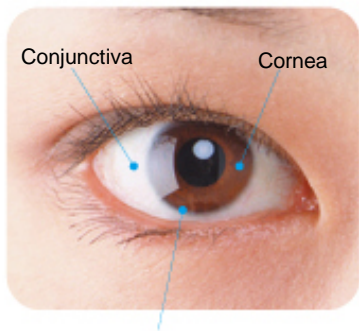
While accelerating the development of its own regenerative medical products, J-TEC aims to contribute to improving patient’s quality of life (QOL) by promoting the practical application of regenerative medicine through custom development of regenerative medical products that supports clinical research, clinical studies, and manufacture.

\* Corneal epithelial stem cell deficiency

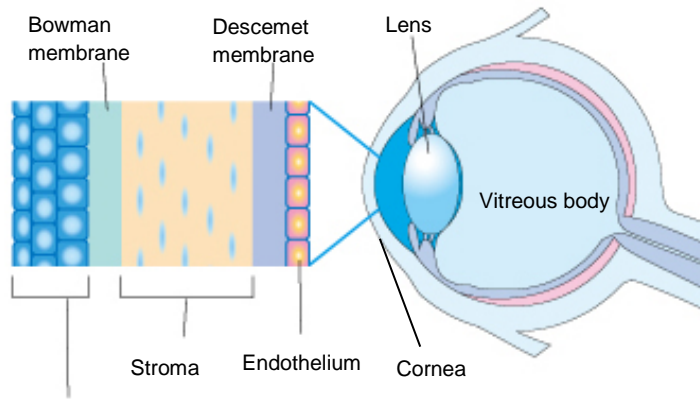
A condition that occurs when the corneal epithelial stem cells that are present in the limbus, which is the boundary between the conjunctiva and cornea, are lost owing to hereditary or external factors.

(Reference Information)

The corneal epithelium is located at the outermost layer of the eye and its source is the corneal epithelial stem cells that are present in the limbus, which is the boundary between the conjunctiva and cornea. When corneal epithelial stem cells are lost, a condition known as corneal epithelial stem cell deficiency occurs, causing the cornea to become cloudy and visual acuity to decline. The causes of corneal epithelial stem cell deficiency may be hereditary, such as aniridia or sclerocornea; external, such as alkaline trauma or burns; endogenous, such as Stevens Johnson syndrome or ocular pemphigoid; or idiopathic.



Limbus: At boundary between conjunctiva and cornea, it is the locus of corneal epithelial stem cells.



Epithelium: The outermost layer of the cornea, it consists of corneal epithelial cells.

For inquiries on information on this press release, contact:

**Japan Tissue Engineering Co., Ltd.**

Corporate Planning Department, Corporate Management Division

TEL :+81-533-66-2020