March 10, 2022
Japan Tissue Engineering Co., Ltd.

The research group from Jikei University School of Medicine and St. Marianna University School of Medicine launched an investigator-initiated clinical trial of autologous nasal mucosal epithelial cell sheets for middle ear cholesteatoma
— J-TEC commissioned with contract manufacture of the IP —

Hiromi Kojima (Department Chairperson), Yutaka Yamamoto (Professor), Kazuhisa Yamamoto (Lecturer), and Tsunetaro Morino (Lecturer) of the Jikei University School of Medicine Department of Otorhinolaryngology / Head & Neck, and Manabu Komori (Lecturer) and others from St. Marianna University School of Medicine has launched an investigator-initiated trial (IIT) of autologous nasal mucosal epithelial cell sheets ; a new treatment for middle ear cholesteatoma.

This IIT is supported by the Japan Agency for Medical Research and Development (AMED) under its Application Research Project for Regenerative Medicine. The research group aims to become the first in Japan to receive marketing approval for a regenerative medical product in the otorhinolaryngology field.

J-TEC (Japan Tissue Engineering Co., Ltd.; President & CEO Ken-ichiro Hata) has been commissioned to manufacturing the investigational product.

Details

【Overview of the Investigator-Initiated Trial】

Middle ear cholesteatoma is a refractory disease in which skin remnants from the external ear canal invade the middle ear, destroying tissue and causing hearing loss, dizziness, facial nerve palsy, meningitis, etc. At present, the only radical therapy is surgery (tympanoplasty), but standard surgical procedures and methods of reliably preventing post-operative recurrence have not yet been established.

The Jikei University School of Medicine – St. Marianna University School of Medicine research group developed a new method that promotes regeneration of the middle ear mucosa post operation by transplanting cell sheets cultured from the patient's own nasal mucosa. Because no adverse events or complications were observed in the clinical studies that were conducted starting in 2014, the research group launched an IIT in November 2021 with the aim of making the IP into a commercial product, and the first transplant was performed on February 1, 2022.

Through this IIT, the group aims to establish highly safe methods for manufacturing and transplanting the cell sheet product that will impose a minimal burden on the patient. **With success, this will be the first product to obtain marketing approval for a regenerative medical product in the otorhinolaryngology field in Japan.**

A second transplant is scheduled in March 2022 at St. Marianna University School of Medicine Hospital. The Jikei University School of Medicine Hospital and St. Marianna University School of Medicine Hospital together plan to conduct a clinical trial involving 12 patients.

For details, please see the press release from the JIKEI University School of Medicine and St. Marianna University School of Medicine.
URL (Japanese only): http://www.jikei.ac.jp/news/press_release_20220310.html

With the vision of “creating a future for regenerative medicine”, J-TEC is contributing to the improvement of patient’s quality of life (QOL) by promoting the creation of a regenerative medicine industry through the continuous development and marketing of new regenerative medical products and medical devices, as well as efforts to further promote the use of its existing products.

(Reference: About J-TEC)

J-TEC is a maker of regenerative medical products whose corporate vision is “creating a future for regenerative medicine,” and has been a member of the Teijin Group since March 2021. As Japan’s top runner in regenerative medicine, J-TEC obtained marketing approval for autologous cultured epidermis “JACE”, Japan’s first regenerative medical product, in October of 2007, and began marketing the product in January of 2009. J-TEC then went on to obtain marketing approval for Autologous Cultured Cartilage “JACC” in July of 2021, for Autologous Cultured Corneal Epithelium “Nepic” in March of 2020, and for Autologous Cultured Oral Mucosal Epithelium “Ocural” in June 2021. “JACC” was Japan’s first regenerative medical product for use in orthopedic surgery, and “Nepic” was the first for use in ophthalmology. Of the 16 regenerative medical products that have been approved in Japan, four are J-TEC products.

Contact information for inquiries about this announcement:
Japan Tissue Engineering Co., Ltd.
Corporate Planning Department, Corporate Management HQ
TEL: 0533-66-2020 Email: jtec-info@jpte.co.jp