November 25, 2021
Japan Tissue Engineering Co., Ltd.

Announcement of Start of Clinical Trial for Allogeneic Cultured Epidermis "Allo-JaCE03"
− J-TEC's first allogeneic cell therapy product: Submitted notification of clinical trial plan to realize ready-made product that can be swiftly provided to patients −

Japan Tissue Engineering Co., Ltd. ("J-TEC", headquarters in Gamagori, Aichi, Japan; President & CEO Ken-ichiro Hata) is pleased to announce that it submitted notification of the clinical trial plan for Allogeneic Cultured Epidermis (development name: "Allo-JaCE03") to the Pharmaceuticals and Medical Devices Agency today.

J-TEC will acquire knowledge and know-how about medical devices through the development of "Allo-JaCE03" and develop new business in fields that use allogeneic cells (cells from other people). With the vision of "creating a future for regenerative medicine", J-TEC is promoting the creation of a regenerative medicine industry and contributing to the improvement of patient quality of life (QOL) by continuously developing and marketing new regenerative medical products and medical devices, in addition to promoting the spread of J-TEC's existing products.

Allogeneic Cultured Epidermis

Details

[Product Description]

"Allo-JaCE03" is dried epidermal cell sheet derived from healthy human skin. Through reconstitution, it returns to the resilient physical properties it had before drying. Its high degree of biocompatibility makes it suitable for use in the promotion of early wound healing.

[Clinical Trial Summary]

The purpose of this clinical trial is to verify the efficacy and confirm the safety of "Allo-JaCE03" in patients with deep dermal burn (DDB), which is a typical skin defect disorder. J-TEC plans to conduct the clinical trial at a total of 5 facilities, including Kyoto University Hospital.

[Product Features]

(1) Because the raw material is allogeneic cells, systematic mass-production of a product that meets certain quality standards is possible.
(2) The dried form of this cultured product means that it can be stored at room temperature for long periods of time. Medical institutions can stock it as a ready-made product (one that is manufactured and stored in advance so that it can be used without delay when needed).
(3) This product is a medical device that does not contain living cells. J-TEC is taking advantage of the product features of allogeneic origin and dried form to accelerate deployment not only within Japan but also to overseas markets.

[Background/History]

J-TEC obtained marketing approval for Japan's first regenerative medical product, autologous cultured epidermis "JACE", in 2007, for the indication of severe thermal burns. When "JACE" was marketed in 2009, the percentage of burn victims whose lives were saved improved. However, with severe thermal burns and other skin defects, it is necessary to close the wound swiftly after the burn is sustained in order to stabilize the patient's general condition. The existing treatment methods had

the following challenges. Development of “Allo-JaCE03” is being promoted to solve these challenges.

(1) “JACE” is a made-to-order product which uses the patient’s own skin as the raw material. It takes 3 weeks to manufacture, and in severe burn cases, it is not uncommon for the patient to die before the skin grafting can be performed.
(2) There are limits to the therapeutic effects of the existing wound covering materials. Autologous skin grafting is highly invasive for the patient.
(3) Because the medical costs associated with the treatment of severe thermal burns are extremely high, it is desirable to shorten the treatment period from the standpoint of social welfare spending.

At the same time, development of allogeneic products involves raw material supply issues. Construction of a system for the productization of J-TEC’s “Allo-JaCE03” and the stable supply of human allogeneic cells was adopted as a subsidized project by the Japan Agency for Medical Research and Development (AMED), and J-TEC is striving to resolve raw material supply issues with funding from the national government.

August 25, 2021: “Announcement: Acceptance of Development Project in FY2021 AMED Program for the Promotion of Innovation through Industrial-Academic Collaboration”
June 15, 2021: Acceptance of Development Project in FY2021 AMED Program for the Development of Basic Technology for the Industrialization of Regenerative Medicine and Gene Therapies (Project for the Promotion of Stable Supply of Human (Allogeneic) Somatic Cell Material for Regenerative Medical Products).

[Earnings Estimate]

J-TEC announced this business plan as part of its “Medium-Term Management Plan (Business Plan and Projects with Growth Potential)”, dated May 11, 2021. The project is proceeding according to plan and will have no effect on the earnings outlook for the term ending in March 2022. J-TEC will promptly announce any new facts that could have a major impact on its business performance.

(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 14 regenerative medical products that have been approved in Japan, four are J-TEC products.

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