

**Announcement : Acceptance of Development Project in FY2021 AMED Program
for the Promotion of Innovation through Industrial-Academic Collaboration**

Japan Tissue Engineering Co., Ltd. (“J-TEC”, headquarters in Gamagori, Aichi Prefecture; President & CEO Ken-ichiro Hata) is pleased to announce the acceptance of its development project submitted under the Japan Agency for Medical Research and Development (AMED) Program for the Promotion of Innovation through Industrial-Academic Collaboration. Through the proposed project, J-TEC aims to create innovative medical devices using human cells, and to contribute to the further development of regenerative medicine in Japan.

For information about the AMED program*, please see the announcement issued by AMED on August 24, 2021.

*The information is in Japanese.

(AMED website) https://www.amed.go.jp/koubo/12/01/1201C_00007.html

Details**[Title of Development Project]**

Development and Commercialization of Dried Allogeneic Cultured Epidermis for Use in Skin Reconstruction

[R&D Representative]

Masukazu Inoie, Executive Officer, R&D Director, Japan Tissue Engineering Co., Ltd.

[Background/History]

In 2007, J-TEC obtained marketing approval for autologous cultured epidermis “JACE”, Japan’s first regenerative medical product, for the indication of severe thermal burns. Beginning in 2009, the market launch of “JACE” led to an improvement in the percentage of patients with severe burns whose lives were saved. However, with severe thermal burns and other skin defects, it is necessary to stabilize the patient’s overall condition by closing the wound soon after injury, and this meant that we faced the following challenges with the existing treatment method.

- ① “JACE” was a product that was made to order, using the patient’s own skin as the raw material, and because it took 3 weeks to manufacture the product, it was not uncommon in severe cases for the patient to die before the transplant could be performed.
- ② There are limits to the therapeutic effect of the existing wound covering materials. Autologous skin transplants are highly invasive for the patient.
- ③ Because the costs of treating severe thermal burns are extremely high, shortening the treatment period is desirable from the standpoint of social benefit spending.

We were called upon to find solutions to these challenges.

[Objectives of This Research]

Through this research, we aim to commercialize allogeneic cultured epidermis for use in skin reconstruction.

This is a ready-made product made using skin from a donor as the raw material. This means that it is manufactured beforehand and kept in storage so that it can be used without delay when necessary. It helps save lives by making it possible to close large-area skin defects like thermal

burns quickly to promote early reconstruction of the skin, and it can improve the functional prognosis by reducing scarring.

Moreover, unlike existing wound covering materials, it has high biocompatibility because it is manufactured from human epidermal cells, and it adheres completely to the wound. It is expected to have a superior wound-healing promotion effect owing to the biologically active substances contained in cells.

Because of its dried form, this product can be sterilized and stored for long periods at room temperature, ensuring safety and convenience. Since it also has the effects of reducing the number of surgical operations required, preventing infections, and shortening hospitalization periods, it can be expected to lighten the burden on healthcare professionals and reduce medical expenses.

[Future outlook]

We expect to have grant income in connection with this project, but the effect of this project on the earnings forecast for the full-year ending in March 2022 is expected to be minor. We will promptly announce any new facts that can be expected to have a substantial effect upon earnings.

Inquiries concerning this topic:
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