

Announcement on the Progress of the Clinical Trial of Allogeneic Cultured Epidermis Allo-JaCE03

Japan Tissue Engineering Co., Ltd. (Headquarters: Gamagori, Aichi Prefecture; President and CEO: Ken-ichiro Hata) is developing Japan's first dried allogeneic cultured epidermis made from the skin tissue of another person (development name: Allo-JaCE03, medical device). We have recently notified the Pharmaceuticals and Medical Devices Agency (PMDA) of the completion of our clinical trial targeted at deep dermal burn^{*1} (hereinafter referred to as "the Trial"). The progress of the Trial is as follows.

1. Overview of the Trial

The Trial was targeted at patients with deep dermal burn and intended to verify the efficacy and safety of Allo-JaCE03. The Trial ended with the treatment and follow-up of all cases completed. We have fixed the data obtained through the Trial concerning the cases and conducted a data analysis with regard to efficacy and safety. The results are outlined below.

2. Key analysis results

- I The primary endpoint was the epithelialization rate^{*2} at the Allo-JaCE03 application site on the 7th day after initial application. This parameter demonstrated a statistically significant improvement compared to the one estimated with existing treatments ($p=0.0123$, Student's t-test).
- I No adverse events of concern were observed.

The Trial showed that, in patients with deep dermal burn, epithelialization was recognized as early as on the 7th day after initial application. No adverse events of concern were observed during about the 3-month period after initial application, which is immensely significant.

*1: Skin burns are classified into three categories by depth: epidermal burn, deep dermal burn, and deep burn. A deep dermal burn, which injures skin deep down to the dermis, takes time to heal and may inflict permanent damage at times. Depending on circumstances, even surgery may be necessary.

*2: The epithelialization rate means the percentage of the epithelialized area where defected skin is re-covered by epidermis.

[Comment from President Ken-ichiro Hata]

This is an Off-The-Shelf product which can be manufactured and stored in advance, and I think it provides a simpler means of treatment of mild degrees of burn injury. Building on the stable cell culture techniques that we have developed over the years has made us ready for mass production. Since this product does not contain living cells, its treatment effect is different from that of the autologous cultured epidermis JACE. So, I think it represents a new step in medicine that the clinical trial has demonstrated the efficacy of the product. We are going to put together the data and submit a marketing approval application as quickly as possible. We will stay committed to the development of regenerative medicine by making full use of the technologies we possess.

About allogeneic cultured epidermis

J-TEC is developing Japan's first allogeneic cultured epidermis made from the skin tissue of another person (development name: Allo-JaCE03). A clinical trial targeted at deep dermal burn has been underway since November 2021, and the treatment and follow-up of all cases have been completed recently.

[Features of the product]

1. Since the raw material is allogeneic cells, systematic mass-production of a product that meets certain quality requirements is possible.
2. Once dried, the cultured product can be stored at room temperature for long periods of time. Medical institutions can keep it in stock so that it can be used without delay whenever needed.
3. Taking advantage of the features of Off-The-Shelf product, J-TEC is going to accelerate the marketing of this product not only in Japan but also in overseas markets.



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