

Notice of Marketing Approval for Autologous Cultured Epidermis "JACEMIN" for the Treatment of Vitiligo

This is to inform you that Japan Tissue Engineering Co., Ltd. ("J-TEC", headquarters in Gamagori, Aichi, Japan; President & CEO, Ken-ichiro Hata) obtained marketing approval for Autologous Cultured Epidermis Maintaining Melanocytes "JACEMIN", a regenerative medical product for the treatment of vitiligo*, on March 17.

JACEMIN is the fifth regenerative medical product launched by our company in Japan. Through JACEMIN, J-TEC will contribute to the improvement of quality of life (QOL) in a greater number of patients while providing them with a new treatment method.

Details

1. Overview of marketing approval

Approval number	30500FZX00001000
Date of approval	March 17, 2023
Generic name	Melanocyte-maintaining human (autologous) epidermis-derived cell sheet
Proprietary name	JACEMIN
Effects or functions	<p>Vitiligo for which nonsurgical therapy is ineffective or not indicated</p> <p><Precautions for use related to effects or functions></p> <ul style="list-style-type: none"> · This product is for use in the treatment of the following: vitiligo vulgaris in which symptoms have been stable for about 12 months, Vogt-Koyanagi-Harada disease, complete depigmentation by chemical substance, and complete depigmentation due to congenital abnormality such as piebaldism. · Selection of patients for whom this product is indicated should be made with a thorough knowledge of the content of the section entitled "Clinical Results" as it pertains to the background of the patients who have been included in clinical trials (vitiligo status, etc.) and results after the transplantation of this product, as well as a thorough understanding of the action mechanism, efficacy, and safety of this product.
Approval conditions	<ol style="list-style-type: none"> 1. Because clinical cases are extremely limited, all-cases post-marketing surveillance must be conducted until the end of the re-examination period in principle, in order to grasp background information on the patients who use this product. At the same time, data on the safety and efficacy of this product should be collected early on, and the necessary measures for proper use of this product should be taken. 2. In light of the risks that accompany heterologous transplantation of the 3T3-J2 cells derived from murine fetuses that are used as feeder cells in the manufacturing process for this product, the necessary measures should be taken to ensure proper handling, such as retaining samples of the final product and records regarding use for 30 years.

2. Product overview

✓ Autologous Cultured Epidermis Maintaining Melanocytes

JACEMIN is autologous cultured epidermis in which the patient's own cutaneous tissue is harvested, and isolated cells cultured to maintain melanocytes are produced in sheet form for use in the patient.



Melanocyte-maintaining human (autologous) epidermis-derived cell sheet JACEMIN

✓ Curing vitiligo with pigment regeneration

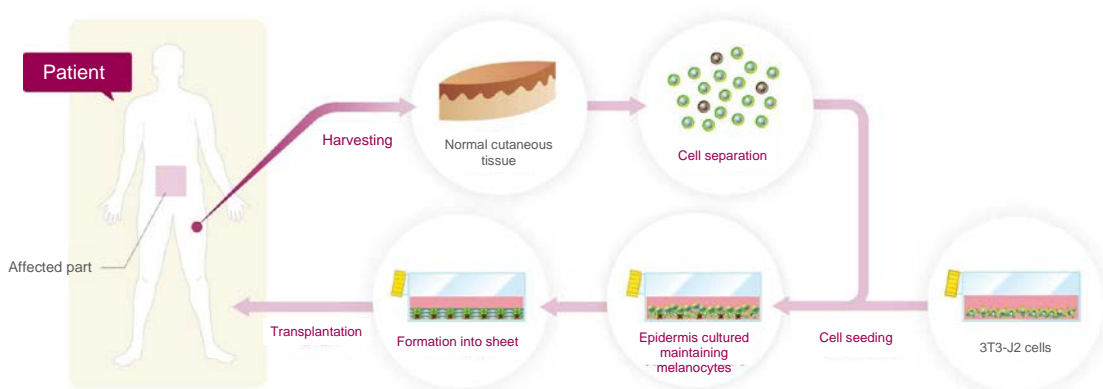
JACEMIN is transplanted into areas affected by vitiligo* where nonsurgical therapy is ineffective or not indicated, after the epidermal layer has been shaved thin. Melanocytes are supplied through transplantation of this product, and its purpose is to regenerate pigment.

✓ Low invasiveness and improvement of quality of life (QOL)

Because JACEMIN grafts are manufactured using a smaller area of cutaneous tissue than in existing surgical therapies, the procedure is low in invasiveness for the patient, and it makes it possible to treat a large area at one time. Moreover, regenerating pigment with this treatment method can be expected to reduce the patient's psychological burden regarding aesthetics and improve patient quality of life (QOL).

* Vitiligo is a disease in which the skin loses color and turns white because of the loss or decrease of pigment cells called melanocytes that are normally present in the skin. This product is for the treatment of vitiligo for which nonsurgical therapies such as topical preparations, oral medications, or phototherapy are ineffective or not indicated, such as acquired vitiligo vulgaris in which there has been destruction of melanocytes and symptoms have been stable for about 12 months, or piebaldism caused by a congenital genetic abnormality. The number of patients with vitiligo vulgaris is estimated at about 150,000 in Japan. Moreover, the incidence of piebaldism is thought to be one in 20,000 to 100,000 people.

(Reference: Transplantation of Autologous Cultured Epidermis Maintaining Melanocytes JACEMIN)



3. Future outlook

J-TEC made its business plan for JACEMIN public in "Medium-Term Management Plan (Matters Related to Business Plans and Growth Potential)" dated March 10, 2022. Because things have been proceeding according to plan, this product approval will not have any effect on our full-year earnings forecast for the term ending in March 2023. We will promptly apprise you of any new facts that would have a major impact on our business performance.

(Reference: About J-TEC)

J-TEC is a maker of regenerative medical products. Our vision is "Creating a Future for Regenerative Medicine", and we have been a member of the Teijin Group since March 2021. As the top runner in Japan's regenerative medicine industry, we provide a stable supply of regenerative medical products, and of the regenerative medical products that have been approved in Japan, the following five are J-TEC products.

- ✓ Approved Oct. 2007: Autologous Cultured Epidermis JACE® – Japan's first regenerative medical product
- ✓ Approved July 2012: Autologous Cultured Cartilage JACC® – Japan's first regenerative medical product in the plastic surgery field
- ✓ Approved March 2020: Autologous Cultured Corneal Epithelium NEPIC® – Japan's first regenerative medical product in the ophthalmology field
- ✓ Approved June 2021: Autologous Cultured Oral Mucosal Epithelium OCURAL®
- ✓ Approved March 2023: Autologous Cultured Epidermis Maintaining Melanocytes JACEMIN

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