

**Submission of CTN for Clinical Trial of
Autologous Cultured Epidermis with Melanocyte, “ACE02” for the Treatment of Leukoderma**

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Japan Tissue Engineering Co., Ltd.

Japan Tissue Engineering Co., Ltd. (a Fujifilm Group company; President: Ken-ichiro Hata, “J-TEC”, hereafter) has submitted clinical trial notification for a trial of autologous cultured epidermis with melanocytes, “ACE02,” to the Pharmaceuticals and Medical Devices Agency (PMDA) today. This trial will involve patients in the stable phase of leukoderma, such as those with vitiligo^{*1} or piebaldism^{*2}.

Through “ACE02”, J-TEC will embark upon the development of regenerative medical products in the field of dermatology, aiming to expand its business beyond the areas of plastic surgery and orthopedic surgery.

Leukoderma is a disease in which a decrease in the melanocytes in the skin causes white patches to form. The need for treatment is particularly high in the case of vitiligo, which is caused by destruction of melanocytes after birth, and piebaldism, where the lack of pigmentation is caused by a congenital genetic anomaly. Treatment for vitiligo presently consists of application of corticosteroids or other topical preparations and exposure of patients to ultraviolet rays. When these are not effective, or in the case of piebaldism, surgical therapy using skin tissue grafts containing melanocytes taken from the patient himself is selected. However, there are problems with surgical therapy in that it is difficult to treat an extensive area evenly in a single procedure because the area of skin tissue that can be harvested is small.

“ACE02” is autologous cultured epidermis manufactured in large sheets that retain the melanocytes after skin tissue is taken from the patient himself. Treatment using “ACE02” aims to restore pigmentation of the affected area.

J-TEC plans to conduct the trial at a total of 7 sites, including Yamagata University Hospital and Nagoya City University Hospital.

J-TEC is also expanding its CDMO/CRO services, utilizing a quality assurance system based on the established technology and knowhow in cell culture that it has accumulated over the years. J-TEC is continuing to accumulate knowledge about leukoderma also through contract manufacture of autologous cultured epidermis for the clinical research conducted at Nagoya City University Hospital.

*1: In vitiligo, destruction of melanocytes after birth causes melanin production to cease or decrease, resulting in depigmentation of the skin. It is estimated that about 150,000 patients in Japan are affected.

*2: Piebaldism is characterized by symmetrical white patches on the forehead, abdomen, knee joints, etc., caused by congenital genetic anomalies. The number of patients in Japan is estimated at several thousand.

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