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Initiation of an Exploratory Clinical Trial with a Muse Cell Product in Patients with Epidermolysis Bullosa

Life Science Institute, Inc.

Life Science Institute, Inc. (Head Office: Chiyoda-ku, Tokyo, President: Seiichi Kiso, hereinafter referred to as “the Company”), which has been promoting the research and development of regenerative medical products using Muse cells, is pleased to announce the initiation of an exploratory clinical trial with the Muse cell-based product CL2020 in patients with epidermolysis bullosa in Japan.

Muse cells (multilineage-differentiating stress enduring cells), which were discovered by a team led by Professor Mari Dezawa at Tohoku University in 2010, are a new type of pluripotent stem cells that can be differentiated into various cells of the human body. Muse cells are natural stem cells originally present in mesenchymal tissues of the body, and have advantageous characteristics, such as few concerns regarding tumor generation, no need to induce differentiation to the target cell and the ability to migrate and accumulate at the site of an injury simply by intravenous administration to engraft and repair the injured tissue.

In experiments using an animal model for skin disease, intravenous administration of CL2020 proved to be effective in reducing the size of the affected area.

Epidermolysis bullosa is a disease where the skin develops blisters and ulcers caused by rubbing of the skin and mucous membranes. The disease results from the inability to withstand force applied to the skin in the course of daily life due to the shortage or lack of adhesion structure molecules responsible for the epidermis - basement membrane - dermis adhesion. It is a designated intractable disease with an estimated 500 to 1,000 patients in Japan. Because there is no effective therapy at present, the development of a new treatment method is desired. CL2020 might suppress skin ulcer formation and ulcer spreading, and therefore might be a new treatment option for epidermolysis bullosa.

[Overview of the clinical trial]

Target disease : Epidermolysis bullosa
Objective of this trial : Study on the safety, tolerability and efficacy of intravenous administration of CL2020 in patients with epidermolysis bullosa.

The Company will continue to develop the healthcare business for the next generation including Muse cells and utilize various resources to further develop its business operations for the realization of a KAITEKI society.