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KANEKA CORPORATION

Kaneka initiates Clinical Trial for Duchenne Muscular Dystrophy using Human (Allogeneic) Amnion-derived Mesenchymal Stem Cells

Kaneka Corporation (Headquarters: Minato-ku, Tokyo; President: Minoru Tanaka) will initiate a Phase I/II clinical trial of human (allogeneic) amnion-derived mesenchymal stem cells*1: KA-301 (hereafter, KA-301) for Duchenne Muscular Dystrophy (referred to below as DMD). This clinical trial is part of the KA-301 development project*2 adopted by the Japan Science and Technology Agency (JST) under the Newly extended TEchnology transfer Program (NexTEP).

DMD is a progressive hereditary neuromuscular disease that causes muscle necrosis due to the lack of normal dystrophin production caused by mutations in the gene encoding the muscle protein dystrophin. To address these highly unmet medical needs, we have been researching a new treatment using KA-301, which was isolated from the amnion at birth. After demonstrating*3 KA-301 in DMD model mice in collaboration with Professor Takashi Okada, Director of the Center for Gene & Cell Therapy at the Institute of Medical Science, the University of Tokyo, we have decided to initiate this clinical trial.
This clinical test will be conducted in collaboration with the National Center of Neurology and Psychiatry (President: Kazuyuki Nakagome) and other medical and research institutions in Japan. Through this clinical trial, we will contribute to the treatment of people with DMD, a serious and progressive hereditary neuromuscular disease.

By accelerating the development of DMD treatment through this clinical trial, we will further strengthen and expand our regenerative and cell medicine-related business*4 including in our group companies. We will continue to actively conduct research and product development that contributes to health.

A scene of R&D

Regenerative Medicine and Cell Therapy Laboratory
(in Kobe MI R&D Center)

*1. Human (allogeneic) amnion-derived mesenchymal stem cells
Undifferentiated cells that exist in amnion isolated from the placenta at birth. They have the ability to differentiate into various mesenchymal cells such as muscle, bone, cartilage, and fat, as well as to self-renew, and are highly immunosuppressive. In addition, they are resistant to rejection and can be easily transplanted into other people. Furthermore, amnion harvesting does not involve any new invasion of the donor, and a large number of mesenchymal stem cells can be obtained from a single piece of amnion, making it suitable for mass production.

*2. Development business for amnion-derived mesenchymal stem cells for pharmaceutical use, which are expected to expand their application to various diseases due to their diverse effects, including anti-inflammatory effects

*3. Nitahara Kasahara Y et al. Immunomodulatory amnion-derived mesenchymal stromal cells preserve muscle function in a mouse model of Duchenne muscular dystrophy. Stem Cell Research & Therapy (2023) 14:108

*4. Biomaster, Inc. (Headquarters: Yokohama City, Kanagawa Prefecture; President: Takuji Hasegawa), a group company, uses its proprietary autologous cell therapy technology in Cellport Clinic YOKOHAMA, that it runs, to provide advanced medical care in the field of plastic surgery, including breast reconstruction, and also provides cells to the same field and the orthopedic surgery field, such as for knee osteoarthritis.