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KANEKA CORPORATION

## Kaneka initiates Clinical Trial for Acute Spinal Cord Injury using Human (Allogeneic) Amnion-derived Mesenchymal Stem Cells

Kaneka Corporation (Headquarters: Minato-ku, Tokyo; President: Minoru Tanaka) has initiated a Phase I/II clinical trial of human (allogeneic) amnion-derived mesenchymal stem cells\*<sup>1</sup>: KA-301 (hereafter, KA-301) for acute spinal cord injury. The cell preparations used in this clinical trial were manufactured using technology developed through a development project\*<sup>2</sup> adopted by the Japan Science and Technology Agency (JST) under the Newly extended TEchnology transfer Program (NexTEP).

Spinal cord injury is a condition resulting from traumatic injuries caused by falls, tumbles, or traffic accidents. Although a certain degree of recovery can be achieved through spinal stabilization and neurological rehabilitation at an early stage after the injury, various residual disabilities such as motor paralysis, loss of sensation, and impairment of bladder and rectal function often coexist, and new treatment methods are expected to be developed. For such intractable conditions, we have been researching a treatment method using KA-301, which is isolated from amniotic membrane at birth. After demonstrating\*<sup>3</sup> KA-301 in acute spinal cord injury model mice in collaboration with Professor Miki Fujimura and Lecturer Masahito Kawabori of the Department of Neurosurgery, Hokkaido University Graduate School of Medicine, we decided to initiate this clinical trial.

The trial will be conducted in collaboration with medical institutions in Japan for the ASIA impairment scale B\*<sup>4</sup> of acute spinal cord injury within 144 hours of injury, with plans to evaluate mainly safety in Phase I and efficacy and safety in Phase II.

The recently announced clinical trial\*<sup>5</sup> for Duchenne muscular dystrophy and this clinical trial will accelerate the development of effective treatments for unmet medical needs and further strengthen and expand our regenerative and cell medicine-related business\*<sup>6</sup> including 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. Takamiya S et al. Intravenous transplantation of amnion-derived mesenchymal stem cells promotes functional recovery and alleviates intestinal dysfunction after spinal cord injury. PLoS One (2022) Jul 8;17(7)

\*4. ASIA (American Spinal Injury Association) impairment scale

A standardized scale that indicates the degree of spinal cord injury in terms of sensory and motor function. There are five levels ranging from A (complete paralysis in both sensory and motor functions) to E (normal in both sensory and motor functions).

\*5. Kaneka initiates Clinical Trial for Duchenne Muscular Dystrophy using Human (Allogeneic) Amnion-derived Mesenchymal Stem Cells

<https://www.kaneka.co.jp/en/topics/news/2023/ennr2307281.html>

\*6. 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.