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Initiation of a Clinical Trial with a Muse Cell Product
in Patients with Spinal Cord Injuries

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 product using Muse cells, is pleased to announce the initiation of a clinical trial with the Muse cell-based product CL2020 in patients with spinal cord injuries in Japan.

Muse cells (multilineage-differentiating stress enduring cells), discovered by Professor Mari Dezawa’s group at Tohoku University in 2010, are a novel type of non-tumorigenic pluripotent stem cells that can be differentiated into various kinds of cells in the body. Muse cells are endogenous reparative stem cells distributed in the peripheral blood, bone marrow and connective tissue of organs. Their advantageous characteristics are represented by low safety concerns, unnecessary of gene introduction or differentiation induction prior to administration and of surgical operation for delivering cells because of their specific ability to accumulate to the damaged site after intravenous administration, enabling treating patients only by intravenous drip of Muse cell preparation, one of the simple expedient approaches.

In 10th thoracic-spinal cord injury animal model, intravenous administration of human product CL2020 proved to be effective in improving motor function of the hind limbs in BBB (Basso-Beattie-Bresnahan) Motor Score.

Symptoms of spinal cord injury depend on the severity of injury and its location on the spinal cord, and may include partial or complete loss of sensory function and/or motor control of limbs and trunk. Current treatment for spinal cord injuries do not deliver sufficient improvement for motor and sensory paralysis, leading to mental, economic and social loss for patients and their family over a long time, and thus effective treatment is a pressing social issue. Because the total number of patients is estimated to be 100,000 to 200,000 with 4,000 to 5,000 people experiencing these injuries annually in Japan, the development of a new treatment method is strongly desired. CL2020 was suggested to improve motor function by intravenous drip and therefore Muse cells are expected to be a new treatment option for patients with severe paralysis from a subacute spinal cord injury.

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[Overview of the clinical trial]

Target disease: Spinal cord injury (subacute)

Objective of this trial: Study on the efficacy and safety of intravenous administration of CL2020
in patients with spinal cord injuries

The Company will continue to develop the healthcare business for the next generation including Muse cells to contribute to the health and medical care of people worldwide for the realization of the KAITEKI where people lead healthy and secure lives.