NewsRelease

NIPPON SHOKUBAI

March 17th, 2022

Completion of the Clinical Research on Knee Osteoarthritis using "MicoCell" 3D Cell Culture Vessel
-Safety of Cell Aggregates Confirmed at our Collaborative Research Clinic-

NIPPON SHOKUBAI Co., Ltd. (Headquarters: Osaka, Japan, President: Yujiro Goto, hereinafter "Nippon Shokubai") and Saiseikai Sobajima Clinic (Location: Osaka, Japan, Director: Satoshi Sobajima, hereinafter "Sobajima Clinic") launched clinical research (safety study) regarding treatment of knee osteoarthritis* by injection of adipose-derived stem cell aggregates produced with MicoCell™, a three-dimensional cell culture vessel developed by Nippon Shokubai in February 2021, and have recently completed it. This clinical research confirmed the safety of the above cell aggregates at Sobajima Clinic.

MicoCell is a three-dimensional cell culture vessel developed by Nippon Shokubai using its proprietary technology, and is characterized by its ability to produce large quantities of cell aggregates with properties similar to those in the living body and a uniform particle size. Nippon Shokubai and Sobajima Clinic have been engaged in joint clinical research to obtain data on the safety and efficacy of human adipose-derived stem cell aggregates produced using MicoCell for treatment of knee osteoarthritis. In this clinical research, cell aggregates were produced from the patient's own adipose-derived stem cells using MicoCell, and were injected into the knee joint. Sobajima Clinic submitted a Type 2 Regenerative Medicine Plan required by the "Act on the Safety of Regenerative Medicine" to the Regenerative Medicine Committee, which was approved then started by the Kinki Regional Bureau of Health and Welfare on December 18, 2020, and a completion report was submitted on February 28, 2022.

More details of this research are available in the Clinical Research Database "Japan Registry of Clinical Trials (https://jrct.niph.go.jp/)," Clinical Research Protocol Number: jRCTb050200097.

In the clinical research at Sobajima Clinic, the safety of cell aggregates was confirmed after administering the cell aggregates produced using MicoCell to a total of five patients. The details of this clinical research will be presented by Director Sobajima at the 21st Congress of the Japanese Society for Regenerative Medicine, which is scheduled to start on March 17.

Presentation at society: The 21st Congress of the Japanese Society for Regenerative Medicine (held online)

Title: Report on the clinical research on the safety of transplantation of subcutaneous adipose-derived stem cell aggregates in knee osteoarthritis treatment

Presenter: Satoshi Sobajima, Director, Saiseikai Sobajima Clinic
Session title: General presentation 20 “Mesenchymal Stem Cells and Somatic Stem Cells 4”
Date and time of session: 13:20 to 14:20, March 19 (Sat.), 2022

In the future, we plan to submit an application for approval and conduct clinical research (effectiveness study) to confirm the efficacy of the cell aggregates.
Through this clinical research, we will contribute to the practical application of treatment using cell aggregates and the further development of regenerative medicine.

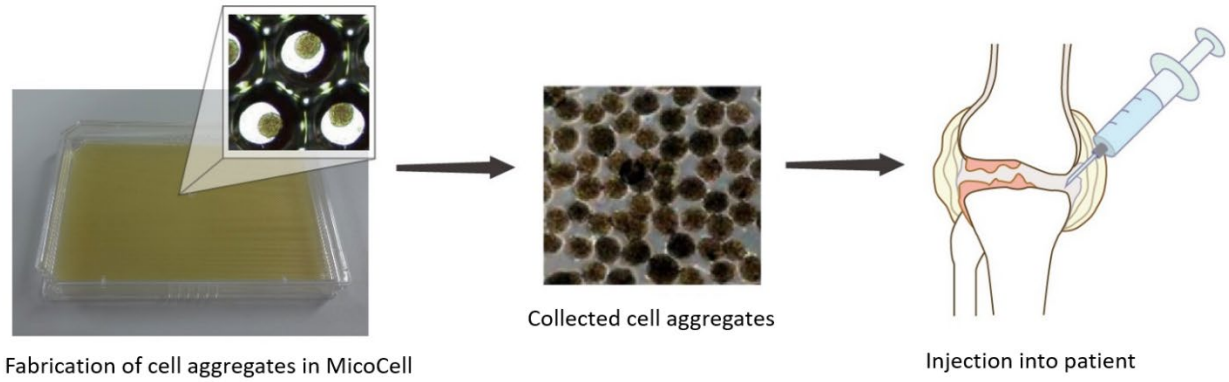

Figure: Outline of clinical research using MicoCell for knee osteoarthritis

*Knee osteoarthritis (OA) involves the wear or loss of cartilage in the knee, leading to deformation of the knee, pain, and swelling. There are approximately 10 million patients in Japan, and over 33 million potential patients with no subjective symptoms in whom knee OA could be confirmed by X-ray diagnosis. Aging is the major cause of knee OA, and the number of patients is therefore increasing with the aging of the population.
Reference: “Report on Measures to Prevent Musculoskeletal Diseases to Promote Long-Term Care Prevention,” July 1, 2008, Study Group on Measures to Prevent Musculoskeletal Diseases to Promote Long-Term Care Prevention, Health and Welfare Bureau for the Elderly, Ministry of Health, Labour and Welfare.

About NIPPON SHOKUBAI Co., Ltd.: Since 1941, Nippon Shokubai has grown up its business with unique catalyst technology. Nippon Shokubai has supplied, for example, ethylene oxide, acrylic acid, automobile catalysts, process catalysts and so on. Among all, our global market share of superabsorbent polymers is the largest in the world now (according to Nippon Shokubai research). Nippon Shokubai is a global chemical company operating under its corporate mission "TechnoAmenity – Providing affluence and comfort to people and society, with our unique technology."
https://www.shokubai.co.jp/en/

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