

May 30, 2023

To whom it may concern

**Commencement of Clinical Research on Knee Osteoarthritis
using Adipose-derived Mesenchymal Stem Cells Cultured with Cellhesion®-MS**

---Joint Research between Nissan Chemical and SOBAJIMA Clinic on Regenerative Medicine---

We, Nissan Chemical Corporation (Head Office: Chuo-ku, Tokyo; President and Representative Director: YAGI Shinsuke, "Company"), are pleased to announce that in the joint research with Incorporated Medical Institute Saiseikai SOBAJIMA Clinic (Head Clinic: Higashiosaka-shi, Osaka; Clinical President and CEO: SOBAJIMA Satoshi, "Clinic"), we commenced in May 2023 the clinical research on knee osteoarthritis (OA) using adipose-derived mesenchymal stem cells cultured with Cellhesion®-MS (Ch-ADSCs) which the Company developed.

On May 9, 2023, the Clinic obtained approval from the Minister of Health, Labor and Welfare for its application for clinical research regarding the adipose-derived stem cells (ADSCs) for treating OA "Knee Osteoarthritis Treatment with 3D-Cultured Adipose-derived Stem Cells" ([jRCT Disclosure System](#), Please search trial ID jRCTb050230021 from "Search for clinical trials"). And on the same day, the research started.

This clinical research is to culture ADSCs harvested from a patient's adipose tissue using Cellhesion®-MS developed by the Company, transplant Ch-ADSCs produced by that culture to the patient, and confirm the safety of the treatment.

Comparing the Ch-ADSCs cultured using Cellhesion®-MS with the plane-cultured mesenchymal stem cells in conventional culture vessels, the Ch-ADSCs show improvements in the potency of accumulation in involved and injured sites, the anti-inflammatory effect, and the angiogenesis potency and other aspects. Therefore, it is expected to exert a higher efficacy on the OA treatment.

Under the collaborative framework with the Clinic, we will further advance examining the application of Ch-ADSCs to regenerative medicine to be employed in medical care not covered by health insurance. In addition, as the Cellhesion®-MS cell production method can be applied for the cell mass production, we expect that method can cut the production cost for cell medicine, thereby contributing to reducing medical expenses.

What is Cellhesion®-MS?

"Cellhesion®-MS" is a culture scaffold with the base of natural polysaccharide. Adding this material to the cell culture medium will form a flocculent suspension scaffold in the medium. Once a cell adheres to that scaffold, the cell will proliferate efficiently in the environment close to that in a living organism and form an aggregate with cell and scaffold. That unique mechanism of cell proliferation and the material character exhibit a synergistic effect, and it is expected to increase cell function and achieve high treatment efficacy.

What is Knee Osteoarthritis (OA)?

“Knee osteoarthritis” is a condition in which the joint bones become loose due to the degeneration or wear-and-tear of ligaments and cartilage of the knee. A patient suffers several symptoms, such as persistent inflammation of synovial tissue in the joint and relapses of the excessive retention of joint fluid and joint pain. Those indications cause the deterioration of surrounding muscles and tendons, consequently, the decline in function and deformation of the knee joint. The OA treatments are broadly categorized into conservation therapy (such as administering drugs and exercise therapy) and operative therapy (such as an artificial joint replacement surgery). But for these years, platelet-rich plasma (PRP) therapy and a stem cell transplant have become widely employed as new options. Those treatment methods are positioned between conservation and operative therapies, and their efficacy has been confirmed to be minimally invasive. Recently, however, a more effective treatment method has been sought.

About SOBAJIMA Clinic:

Since 2016, the SOBAJIMA Clinic (“Clinic”) has offered various methods of regenerative medicine, including stem cell transplants, mainly in orthopedic diseases. In 2018, it opened its own cell culture and processing facility and established the structure to enable the whole process, from harvesting, processing, and transplanting cells, to complete in its facility. The Clinic has actively engaged in a wide spectrum of research and development, from fundamental to clinical studies, working with multiple companies and universities. The results of such research studies are reported at the relevant academic conferences and published in the scientific works of literature ([Sobajima S - Search Results - PubMed \(nih.gov\)](#)). (<https://soba-cli.com/> Japanese Only)

About Nissan Chemical Corporation:

Nissan Chemical Corporation’s vision is to become a corporate group that contributes to the protection of the global environment, the wellbeing of humanity and valued by society. In that aim the Planning and Development Division’s mission is to create new products and businesses in the following domains; Information and Communication, Environment and Energy and Health Care. Products developed for these domains will utilize highly novel technologies to meet market and societal needs.

(<https://www.nissanchem.co.jp/eng/>)

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