

To whom it may concern

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Notice of Grant of a Japanese Patent for the Method for Obtaining Induced Smooth Muscle Cells

We hereby announce that the registration of a patent in Japan for the “Method for Obtaining Induced Smooth Muscle Cells,” filed by our Austrian subsidiary (Innovacell GmbH) has been completed.

This patent is related to ICEF16, an investigational product in the Innovacell Group's developmental pipeline for the treatment of passive fecal incontinence. The grant of the patent is noteworthy as it enhances the commercial potential of ICEF16 in Japan.

■ Overview of the Patent

[Patent Number]	No. 791078
[Patent Registration Date]	August 17, 2026
[Title of the Invention]	Method for Obtaining Induced Smooth Muscle Cells
[Patentee]	Innovacell GmbH

■ Overview of ICEF16

This patent is related to ICEF16, a pipeline product currently being developed by the Innovacell Group for the treatment of passive fecal incontinence.

Fecal incontinence is defined as the involuntary or unintentional leakage of stool from the anus, and it is said that there are approximately 5 million patients suffering from fecal incontinence in Japan (Source: website of the Japan Society of Coloproctology). Symptoms of fecal incontinence are classified into urge fecal incontinence, passive fecal incontinence, and mixed fecal incontinence, in which both symptoms coexist. Among these, passive fecal incontinence is characterized mainly by involuntary stool leakage without the sensation of urgency. This form of incontinence is typically caused by dysfunction of the internal anal sphincter. According to a paper published in an academic journal (Toshiki Mimura et al., "Survey Report on the Actual Status of Fecal Incontinence Care in Japan -Current Status of Diagnosis and Treatment-," Journal of the Japan Society of Coloproctology, 65: 101–108, 2012), more than 80% (approximately 84%) of patients with fecal incontinence have passive-type symptoms.

The cells used in ICEF16 are autologous induced smooth muscle-like cells (iSMCs) manufactured from skeletal muscle tissue obtained from the patient. As the direct isolation and large-scale expansion of native smooth muscle cells is technically challenging, the ICEF16 manufacturing process first generates and expands skeletal muscle-derived myogenic progenitor cells. These cells are subsequently subjected to a defined transdifferentiation process to obtain a cell population with

smooth muscle-like characteristics.

■ Development Status of ICEF16

ICEF16 is currently in the pre-clinical development stage and is being advanced in preparation for the initiation of a First-in-human Phase I/II clinical trial.

In preclinical studies conducted in a small-animal model (mice), administered skeletal muscle-derived smooth muscle cells were shown to be integrated into smooth muscle tissue at the injection site and express proteins associated with smooth muscle function. Comparable studies are currently underway in a large-animal model (mini pigs).

■ Significance of the Patent

The patent covers an invention relating to a population of induced smooth muscle cells derived from skeletal muscle-derived myogenic progenitor cells used in ICEF16 (i.e., a product invention). Together with Japanese Patent No. 7616665, obtained in 2025 for an invention relating to a manufacturing method entitled “In Vitro or Ex Vivo Method for Obtaining Induced Smooth Muscle Cells,” the newly granted Japanese patent protects key aspects of this manufacturing approach for obtaining induced smooth muscle-like cells from skeletal muscle-derived cells and further strengthens the intellectual property position supporting the ICEF16 manufacturing technology.

■ About Innovacell Inc. (<https://innovacell.com/?lang=en>)

Innovacell Inc. traces its origins to a regenerative medicine company spun out from the Medical University of Innsbruck in Austria. The Company was established in Japan in 2021 as the parent company of that Austrian business (now Innovacell GmbH).

Innovacell Group aims to improve patients' health and quality of life (QOL) through the development and commercialization of cell therapies and regenerative medicine. It is currently focused on developing and commercializing regenerative medicine products for the treatment of urge and passive fecal incontinence as well as stress urinary incontinence.

ICEF15, the most advanced of the Group's pipeline products, aims to treat urge fecal incontinence by regenerating muscle tissue via the local administration of a patient's own skeletal muscle-derived cells (myoblasts). ICEF15 is currently undergoing a multi-regional Phase III clinical trial in the U.S., 11 European countries, and Japan.

To date, Innovacell GmbH has completed multiple clinical trials in Europe, including Phase IIb trials for ICEF15 (urge fecal incontinence) and ICES13 (stress urinary incontinence).

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