

To whom it may concern

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## **Notice Regarding the Registration in Japan of a Pharmaceutical Composition Patent Relating to Myoblasts for Use in the Treatment of Anal and Fecal Incontinence**

We hereby announce that the patent application relating to a pharmaceutical composition containing myoblasts for use in the treatment of anal and fecal incontinence in a specific patient group (hereinafter, the "Patent"), which had been filed by our Austrian subsidiary (Innovacell GmbH), has been registered in Japan, as published in the Patent Gazette of the Japan Patent Office (issued on June 8, 2026).

The Patent is a patent relating to ICEF15, which targets urge fecal incontinence, which is a part of the Innovacell Group's developmental pipeline. The registration of the Patent is noteworthy as it enhances the commercial potential of ICEF15 in Japan.

### **■ Overview of the Patent**

|                                    |                                                                                                                |
|------------------------------------|----------------------------------------------------------------------------------------------------------------|
| [Title of Invention]               | Myogenic progenitor cells for use in an optimized method for the prevention and treatment of anal incontinence |
| [International Application Number] | PCT/EP2022072088                                                                                               |
| [Patent Holder]                    | Innovacell GmbH                                                                                                |

### **■ Overview of ICEF15**

The Patent relates to ICEF15, which is a part of the Group's pipeline targeting urge 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, urge fecal incontinence is characterized mainly by the inability to hold stool for the short time required to reach the toilet despite feeling the urge to defecate, and it is considered to be commonly caused by dysfunction of the external 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), slightly more than half (approximately 51%) of fecal incontinence patients have urge-type symptoms.

The Innovacell Group is currently advancing the development of ICEF15, which targets urge fecal incontinence, as one of its pipeline products for fecal incontinence. The cells used in ICEF15 are

autologous skeletal muscle-derived cells (aSMDC), which are manufactured from tissue collected from the patient him- or herself. These are myoblasts (progenitor cells that give rise to the muscle fibers constituting skeletal muscle) differentiated and proliferated from satellite cells, the stem cells of muscle tissue.

#### ■ Significance of the Patent

The Patent relates to the autologous skeletal muscle-derived cells (myoblasts) for use in the treatment of anal and fecal incontinence in a specific patient group and provides patent protection for ICEF15 to the extent of the granted claims. The registration of the Patent in Japan can be regarded as enhancing the commercial potential of ICEF15 in Japan.

#### ■ About Innovacell Inc. (<https://innovacell.com/>)

The predecessor of Innovacell Inc. was a cell therapy start-up company spun out from the Medical University of Innsbruck (Austria). Innovacell Inc. was established in Japan in 2021 as the parent company of said Austrian company (currently Innovacell GmbH).

Innovacell group aims to improve patient health and 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 myoblasts. ICEF15 is currently undergoing a multi-regional Phase III clinical trial in 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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