November 9, 2026

To whom it may concern

Company Name: Innovacell Inc.
Representative: Representative Director and Co-CEO
Colin Novick
Representative: Representative Director and Co-CEO
Jason Sieger
(Securities Code: 504A, Growth Market of the Tokyo Stock Exchange)
Point of Contact: Director and CFO Yasushi Hosono
(https://innovacell.com/contact/?lang=en)

Notice Regarding the Submission of a Clinical Trial Application for the Phase I Clinical Trial of ICEF16, a Cell Therapy Product Targeting Passive Fecal Incontinence

We are pleased to announce that on November 6, 2026 (CET), we submitted a Clinical Trial Application (CTA) to the Austrian Federal Office for Safety in Health Care (BASG) to initiate a Phase I clinical trial of ICEF16, a cell therapy product intended to treat passive fecal incontinence.

1. Overview of ICEF16

ICEF16 is a cell therapy product currently under development for passive fecal incontinence caused by weakness or damage of the internal anal sphincter, which is composed of smooth muscle. ICEF16 is intended to treat sphincter dysfunction through ultrasound-guided injection of smooth muscle-like cells (I-SMCs) into the internal anal sphincter. The I-SMCs are produced by harvesting cells from the patient's own skeletal muscle and culturing them to induce differentiation.

This is a First-in-Human (FIH) trial in which ICEF16 will be administered to humans for the first time. With the start of this trial, ICEF16 will become the third program in our Group's pipeline to reach the clinical stage of development.

2. Overview of This Clinical Trial

Trial Phase and Design	Phase I, single-arm, open-label, interventional trial
Country / Number of Sites	Austria, single-centre
Target Enrollment	15 patients
Primary Endpoints	Safety, tolerability, and technical feasibility
First Patient Enrollment (Planned)	First quarter of 2027
Positioning	First-in-human (FIH) trial for ICEF16
Clinical Trial Code / EU CT Number	IC-03-03-1-001 / 2026-528594-44-00
Sponsor	Innovacell GmbH (a subsidiary of our company)
Study Site	Medical University of Graz / University Hospital Graz (Austria)
Secondary / Exploratory Endpoints	Exploratory endpoints (number of fecal incontinence episodes/week, severity, quality of life, anal resting pressure, etc.)
Duration per Patient	9 months + 12 months long term follow-up

■ **About Innovacell:**

Innovacell Inc. was established in Japan in 2021 as the parent company of a regenerative medicine company spun off from the Medical University of Innsbruck in Austria, and was listed on the Tokyo Stock Exchange Growth Market in February 2026 (Securities Code: 504A).

Our Group aims to improve people's health and quality of life through the commercialization of cell therapy and regenerative medicine, and we are currently engaged in the research, development, and commercialization of regenerative medicine products for the treatment of incontinence (urge fecal incontinence, passive fecal incontinence, and stress urinary incontinence). To date, our Group has completed multiple clinical trials in Europe (including late-stage Phase II trials) for two pipeline programs: ICEF15 (target indication: urge fecal incontinence) and ICES13 (target indication: stress urinary incontinence). For more details, please visit our website or our YouTube channel.

End