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To whom it may concern

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Announcement Regarding Completion of FDA IND Review and Approval to Include U.S. Sites and Patients in the ICEF15 Multi-Regional Phase III Fidelia Trial

Innovacell Inc. hereby announces that the U.S. Food and Drug Administration (FDA) has completed its 30-day review of the Investigational New Drug (IND) application submitted for the U.S. participation in the ongoing multi-regional Phase III clinical trial of ICEF15 (the Fidelia Trial), which is currently being conducted in Europe and Japan. Following the completion of the FDA review, Innovacell has received notification that the study may proceed in the United States, enabling the formal inclusion of U.S. clinical sites and patients in the Fidelia Trial.

ICEF15, the most advanced candidate in our Group's pipeline, aims to provide a potential curative treatment for urge fecal incontinence by locally administering the patient's own skeletal muscle-derived cells to the external anal sphincter to promote muscle repair and regeneration. Fecal incontinence is defined as the involuntary or uncontrolled leakage of stool from the anus, and it is estimated that approximately 5 million patients in Japan suffer from this condition (Source: Website of the Japanese Society of Coloproctology). According to a paper published in a specialized medical journal (Toshiki Mimura et al., "Report on a Survey of the Current Status of Fecal Incontinence Care in Japan—Current Status of Diagnosis and Treatment"—Journal of the Japanese Society of Coloproctology 65:101–108, 2012), slightly more than half (approximately 51%) of patients with fecal incontinence exhibit urge incontinence symptoms. For patients with urge fecal incontinence who do not respond adequately to conservative therapies (such as medication), surgical treatments (such as anal sphincteroplasty and sacral nerve stimulation) are typically indicated; however, existing surgical treatments are considered highly invasive (placing a significant burden on the patient's body) and may sometimes be insufficiently effective. ICEF15 has the potential to serve as a treatment alternative for patients who do not achieve sufficient results with conservative therapies, offering lower invasiveness and the prospect of greater efficacy.

The Innovacell Group is currently conducting the Fidelia trial, the pivotal Phase III study representing the final stage of clinical development for ICEF15, across 11 European countries and Japan. The Fidelia trial is a multi-center, placebo-controlled, randomized, double-blind comparative trial in which a total of 290 patients are assigned in a 1:1 ratio to two groups (study drug and placebo). The trial is designed to evaluate the efficacy and safety of ICEF15, with the primary endpoint being the change in the frequency of fecal incontinence at 12 months post-administration compared to baseline. As of June 30, 2026, a total of 250 patients (preliminary figure) had been enrolled, representing approximately 86% of the planned enrollment target of 290 patients.

Following completion of the FDA's IND review and receipt of notification that the study may proceed in the United States, the Fidelia Trial can now be advanced as a global Phase III clinical trial that includes the United States – the world's largest pharmaceutical market. The Innovacell Group has already begun preparations with multiple U.S. clinical sites to participate in the Fidelia Trial and plans to submit the additional documentation requested by the FDA within the required timeframe. At present, the Company continues to target completion of patient enrollment in the Fidelia Trial, including U.S. patients, by the end of 2026.

This represents an important development milestone in the execution of the Fidelia Trial's previously announced global development strategy.

To the best of our knowledge, it is uncommon for a biotechnology venture company to independently conduct a Phase III clinical trial enrolling a large number of patients. Examples of such companies independently conducting a Phase III trial spanning all three major pharmaceutical markets - the United States, Europe, and Japan – are even more limited. Since its founding, the Innovacell Group has pursued global clinical development and business expansion as a core strategic objective, and the inclusion of the United States in the Fidelia Trial represents another step in executing that strategy.

■ Reference Information

Additional information regarding the Fidelia Trial is available on ClinicalTrials.gov.

- ClinicalTrials.gov Identifier: NCT04976153
- URL: <https://clinicaltrials.gov/study/NCT04976153>

■ 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 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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