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To whom it may concern:

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Announcement Regarding Patient Enrollment Status of the ICEF15 Multi-Regional Phase III Clinical Trial (Fidelia Trial) and Completion of Patient Recruitment in Japan and Europe

1. Progress of Patient Enrollment in the ICEF15 Multi-Regional Phase III Clinical Trial

ICEF15 is the most advanced candidate in our pipeline, and we are currently conducting a Multi-Regional Phase III clinical trial of ICEF15 (the “Fidelia Trial”) in the United States, Japan, and 11 European countries.

We plan to complete patient enrollment in the Fidelia Trial by the end of fiscal year 2026 and have established a target enrollment of 290 patients. To date, we have regularly disclosed enrollment progress through quarterly financial results, our corporate website (<https://innovacell.com/business/pipeline/icef15/?lang=en>) and so on.

As disclosed in our Consolidated Financial Results for the Second Quarter of the Fiscal Year Ending December 31, 2026, disclosed on August 6, 2026, the number of enrolled patients stood at 271 as of July 29, 2026. Based on the status of patients currently undergoing screening for eligibility in Japan and Europe, we expect the number of enrolled patients to reach approximately 285 by mid-August 2026 (August 13), although this number may vary depending on screening outcomes and other factors. The background is that the patient enrollment in Japan and Europe over the past few months has progressed at a faster-than-expected pace, bringing us closer to the target enrollment of 290 patients sooner than planned.

2. Advancement of U.S. Enrollment and Completion of Patient Recruitment in Japan and Europe

As noted above, patient enrollment has progressed to a level approaching the target enrollment of 290 patients. At the same time, we are actively advancing preparations to include U.S. sites and patients in the Fidelia Trial in order to bring ICEF15 to patients in the United States as quickly as possible. (Please see “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,” announced on July 2, 2026, for details.)

Since our founding, global development and commercialization have been core elements of our strategy. The inclusion of U.S. patients in the Fidelia Trial is fully aligned with this strategy.

Accordingly, we intend to complete enrollment in the Fidelia Trial in a manner consistent with our previously disclosed global development plan, including a certain number of patients from the United States.

On the other hand, the target enrollment number in a clinical trial is determined in the protocol confirmed with the relevant regulatory authorities, based on the number of patients required to statistically demonstrate efficacy while avoiding unnecessary participation by patients in a trial that involves both burden and risk. Accordingly, increasing the target enrollment would require protocol amendments and regulatory procedures in Japan, Europe, and the United States, which we do not currently intend to pursue.

As a result, continuing recruitment in Japan and Europe would reduce the opportunity to include U.S. patients in the trial. For this reason, we hereby announce that patient recruitment in Japan and Europe was completed as of July 31, 2026.

3. **Outlook for Final Number of Patients To Be Enrolled**

We have conducted the Fidelia Trial under a protocol that specifies a target enrollment of 290 patients as the number required to statistically demonstrate the efficacy of ICEF15. This target enrollment number of patients is set to aim securing sufficient number of patients for the efficacy analysis population and includes a certain number of patients who may withdraw from the trial before treatment for personal reasons and who therefore may not be included in the efficacy analysis population.

The protocol permits replacement enrollment of additional patients when such cases occur. By utilizing this patient replacement mechanism, Innovacell group plans to proceed with enrolling U.S. patients while maintaining the sample size and statistical power necessary for evaluating efficacy and safety. In such case, the final number of enrolled patients may exceed 290 to a certain extent, however, this makes it possible for us to avoid the time and financial burdens associated with additional regulatory compliance and changes to test plans.

4. **Outlook for Timing of Last Patient In**

As described above, we aim to complete enrollment of all patients in the Fidelia Trial while including a certain number of patients from the United States and to conduct the Fidelia Trial as a truly global Phase III trial that includes the United States. The expected timing for completion remains unchanged from our previously disclosed plan and is expected by the end of fiscal year 2026.

■ **About ICEF15**

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).

Urge fecal incontinence is characterized by the inability to retain stool after sensing the urge to defecate and is often caused by damage to the external anal sphincter, leading to involuntary

leakage despite conscious effort to prevent it.

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.

■ **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 United States, 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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