

## Info Sheet for Technical description

No. 0005 - 1

### Organization

\* Mandatoty fields

Name of Organization*	Innovacell K.K.	
Address, City, States, Zip, Country*	MEGURO VILLA GARDEN 5F, 3-5-11 Kamiosaki, Shinagawa-ku, Tokyo 141-0021 JAPAN	
URL	<a href="https://www.innovacell.co.jp/">https://www.innovacell.co.jp/</a> <a href="https://innovacell.com/">https://innovacell.com/</a>	
Brief Descriptions of Organization* (Approx. 100 words)	Innovacell is a late-stage Japanese biotech (with Austrian roots) developing cell therapy treatments for incontinence. Our lead product, ICEF15, is an autologous skeletal myoblast treatment for urge fecal incontinence and is currently in a multi-regional phase III clinical trial across Europe and Japan (EudraCT Number: 2021-001376-42   ClinicalTrials.gov Identifier: NCT04976153   Japan Registry of Clinical Trials ID: jRCT2033230027). This Phase III study is being conducted on the back of 3 successful trials, including the most recent European Phase IIb trial (PMID: 35961517 DOI: 10.1016/j.cgh.2022.07.039) where we were able to show a statistically significant difference between the high cell count cohort and the vehicle cohort. We also have 5-year follow-up data on 10 subjects that participated in an earlier Phase I/II trial (PMID: 25773013 DOI: 10.1111/codi.12947) which combined with the Phase IIb results hints at a clinically efficacious and long-lasting treatment for a traditionally underserved indication area.	
Contact address	Name*	Jason David Sieger
	Department* / Position	Representative Director   COO
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### What kind of technology do you want to offer? \*

- A.** Clinical Development Pipelines → Please see **Sheet [A]**
- B.** Regenerative Medicine-related Consumables / Instruments / Materials / CDMO Services etc. → Please see **Sheet [B]**
- C.** Platform Technologies(\*) that are not included in the above (Group B) → Please see **Sheet [C]**
- \* Peripheral technologies that contribute to a significant improvement in productivity throughout the value chain of pharmaceuticals, from research and development to manufacturing and ultimately market launch.

### If you agree to the following, please check "Yes" below. \*

The technologies introduced in this 'Info Sheet' are in the public domain, as they have been published in research papers or have related patent applications.

- Yes

### Do you have any collaborations/partnerships with pharmaceutical companies?

- Yes
- No

### If you have already received funding from VCs or other sources, up to which stage has the investment round progressed?

- Angel / Seed (including AMED/JST grants)
- Series A
- Series B
- Series C
- Series D or further advanced stages

### Do you agree to leave your presentation materials at FIRM hands and entrust us to make use of them for the purpose of promoting your partnering opportunities? \*

Options*	Comments
<input checked="" type="checkbox"/> Yes	
<input type="checkbox"/> No	

Filled in by\*

Date\*

Colin Lee Novick (Representative Director | CEO)

14-Sep-23

**Sheet [A]** Clinical Development Pipelines**Info Sheet for Technical overview**

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\* Mandatoty fields

**Title\***ICF15**Development Phase\***

- |   |  |  |
|---|--|--|
| <input type="checkbox"/> Basic Research           | <input type="checkbox"/> Drug Discovery            | <input type="checkbox"/> Pre-Clinical                          |
| <input type="checkbox"/> Clinical Trial (Phase I) | <input type="checkbox"/> Clinical Trial (Phase II) | <input checked="" type="checkbox"/> Clinical Trial (Phase III) |
| <input type="checkbox"/> Review                   | <input type="checkbox"/> Others                    |  |

**Disease Area\***

- |  |   |   |
|--|---|---|
| <input type="checkbox"/> Cancer          | <input type="checkbox"/> Central nervous system     | <input type="checkbox"/> Ophthalmology  |
| <input type="checkbox"/> Musculoskeletal | <input type="checkbox"/> Endocrine / Metabolism     | <input type="checkbox"/> Cardiovascular |
| <input type="checkbox"/> Urogenital      | <input checked="" type="checkbox"/> Digestive organ | <input type="checkbox"/> Blood          |
| <input type="checkbox"/> Infection       | <input type="checkbox"/> Dermatology                | <input type="checkbox"/> Immunity       |
| <input type="checkbox"/> Otolaryngology  | <input type="checkbox"/> Respiratory                | <input type="checkbox"/> Others         |

**Description\***

Autologous skeletal muscle-derived cell implantation for the treatment of urge fecal incontinence. Currently conducting a multi-regional phase III clinical trial in 10 European countries and Japan with an aim to use the resulting data to obtain full approval in Europe and Japan

**KEY PUBLICATIONS**

- Frudinger et al 2010: Muscle-derived cell injection to treat anal incontinence due to obstetric trauma: pilot study with 1 year follow-up
- Frudinger et al 2015: Autologous skeletal-muscle-derived cell injection for anal incontinence due to obstetric trauma: a 5-year follow-up of an initial 10 patients
- Frudinger et al 2018: Skeletal muscle-derived cell implantation for the treatment of sphincter-related faecal incontinence
- Thurner et al 2018: Development of an in vitro potency assay for human skeletal muscle derived cells
- Frudinger et al 2022: Skeletal Muscle-Derived Cell Implantation for the Treatment of Fecal Incontinence: A Randomized, Placebo-Controlled Study

**Filled in by\***

Colin Lee Novick (Representative Director | CEO)

**Date\***

14-Sep-23