Info Sheet for Technical description

No. 0005 - 2

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	https://www.innovacell.co.jp/ https://innovacell.com/	
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
	E-mail* / TEL	jason@innovacell.co.jp

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 Servicies 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 advenced 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
☑ Yes	
☐ No	

Filled in by*	Colin Lee Novick (Representative Director | CEO)
Date*	14-Sep-23

Ver.1.0

Sheet【A】 Clinical Development Pipelines

Info Sheet for Technical overview

No. 0005 - **2**

* Mandatoty fields

Title*

ICEF16

Development Phase*

☐	Basic Research	☐	Drug Discovery	☑	Pre-Clinical
☐	Clinical Trial (Phase I)	☐	Clinical Trial (Phase II)	☐	Clinical Trial (Phase III)
☐	Review	☐	Others		

Diesease Area*

☐	Cancer	☐	Central nervous system	☐	Ophthalmology
☐	Musculoskeletal	☐	Endocrine / Metabolism	☐	Cardiovascular
☐	Urogenital	☑	Digestive organ	☐	Blood
☐	Infection	☐	Dermatology	☐	Immunity
☐	Otolaryngology	☐	Respiratory	☐	Others

Description*

Autologous skeletal muscle–derived smooth muscle cell implantation for the treatment of passive fecal incontinence. Currently preparing for a first-in-human (FIH) trial in 2024.

KEY PUBLICATIONS
- Thurner et al 2020: Generation of myogenic progenitor cell–derived smooth muscle cells for sphincter regeneration

Filled in by*	Colin Lee Novick (Representative Director | CEO)
Date*	14-Sep-23