Info Sheet for Technical description

No. 0008 - 2

Organization

* Mandatoty fields

Name of Organization*	Metcela Inc.	
Address, City, States, Zip, Country*	CYBERNICS MEDICAL INNOVATION BASE-A 129, 3-25-16 Tonomachi, Kawasaki-ku, Kawasaki-shi, Kanagawa 210-082	
URL	https://www.metcela.com/en/	
Brief Descriptions of Organization* (Approx. 100 words)	Metcela Inc., established in 2016, is a clinical-stage biotechnology startup pioneering the research and development of fibroblast and stem cell-based therapy for chronic diseases that currently have limited therapeutic options. MTC001 is a combination product of autologous cardiac cells (VCAM-1-positive Cardiac Fibroblast, VCF) and a novel catheter delivery system targeting chronic heart failure patients. MTC001 offers two major advantages over other cell therapies: (1) the therapeutic cells are autologous (patient-derived) and homologous (tissue-specific i.e. cardiac-derived), which is most suitable for the heart, as it is a highly immunogenic organ, and (2) the minimally invasive catheter system is equipped with a highly functional injection needle specifically designed for this therapy to achieve reliable and safe administration of the cells.	
Contact address	Name*	Metcela Corporate Development
	Department* / Position	Corporate Development Dept.
	E-mail* / TEL	cd@metcela.com

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*	Keiji Arimura, CFO
Date*	2023/9/14

Ver.1.0

Sheet【A】 Clinical Development Pipelines

Info Sheet for Technical overview

No. 0005 - 2

* Mandatoty fields

Title*

Revolutionizing Pediatric Cardiac Care: Self-Transplant Therapy with Cardiac Stem Cells

Development Phase*

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

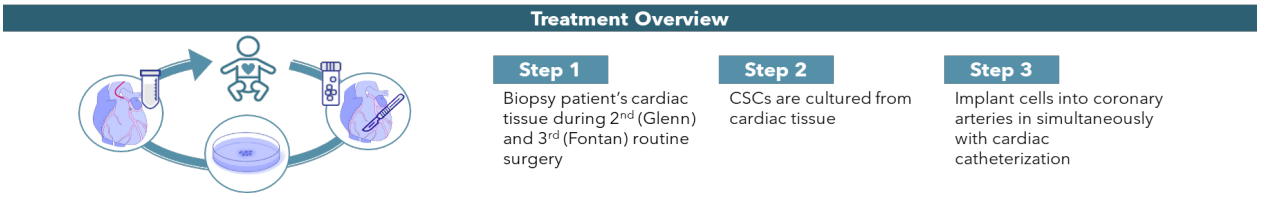
Diesease Area*

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

Description*

One of our lead pipeline, JRM-001, is autologous cardiac stem cell-based product for rare pediatric congenital heart disease. It was designated the Sakigake and Orphan designation by the Japanese government. JRM-001 is currently in Ph3 randomized, controlled, multicenter trial in Japan.

JRM-001 is autologous cardiac stem cell-based product for patients with single ventricle. Single ventricle is a rare pediatric congenital heart disease where the patients are born with only one functioning ventricle, instead of two. These patients go through multiple surgical procedures during their early childhood to repair the anatomical abnormalities to improve and help with the systemic circulation of blood. However, the long-term prognosis is still an issue for these patients as 32% of patients end up developing some kind of cardiac disease, including heart failure.
Thus we see a great need for radical treatment that can improve the long-term prognosis for these young patients.
Even though JRM-001 is an autologous therapy, it requires no additional surgery to obtain the starting tissue as the biopsy is conducted during a required surgery. The cell administration is also coupled with a routine cardiac catheter examination. The long-term safety and efficacy of JRM-001 has already been observed during its Phase 1 and 2 clinical studies conducted at Okayama University. Currently Metcela is conducting Phase 3 trial for JRM-001.



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