Ver.1.0

Info Sheet for Technical description

No. 0003

Organization

* Mandatoty fields

Name of Organization*	Heartseed Inc.	
Address, City, States, Zip, Country*	Seavans 5F, Shibaura 1-2-3, Minato-Ku, Tokyo, 105-0023, Japan	
URL	https://heartseed.jp/en/index.html	
Brief Descriptions of Organization* (Approx. 100 words)	Heartseed Inc. was founded in 2015 to develop and commercialize cardiac remuscularization therapy developed by Prof. Keiichi Fukuda and his group at the Department of Cardiology, Keio University, Japan. Heartseed has proprietary technologies throughout the entire manufacturing process of the cardiomyocyte product, including purification, cell delivery and iPSC production. Heartseed announced the collaboration and license agreement with Novo Nordisk A/S for HS-001 in 2021. Heartseed received "Minister of Science and Technology Policy Award" at Japan Venture Awards 2021, "Ministry of Education, Culture, Sports, Science and Technology Award" at Academic Startups 2021, and "Most Promising Pipelines Awards (iPSC)" at Asia Pacific Cell & Gene Therapy Excellence Awards 2022.	
Contact address	Name*	Taro Noguchi
	Department* / Position	Corporate Planning / Manager
	E-mail* / TEL	taro.noguchi@heartseed.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*	Taro Noguchi
Date*	Sep. 19th, 2023

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Sheet【A】 Clinical Development Pipelines

Info Sheet for Technical overview

No. 0003

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Title*

HS-001 (iPSC-derived cardiomyocyte spheroids)

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*

HS-001, is allogeneic iPSC-derived, highly purified ventricular cardiomyocyte spheroids. By forming micro-tissue-like spheroids, retention rate and viability of cell transplant are improved. The spheroids are transplanted using a special administration needle (SEEDPLANTER®) and guide adapter developed for safe and efficient administration of the spheroids into the myocardial layer of the heart.
The expected mechanism of action is that the transplanted cardiomyocytes electrically couple with the patient's myocardium to improve cardiac output by remuscularization, and secretion of angiogenic factors to form new blood vessels around the transplant site (neovascularization).
HS-001 is under phase 1/2, open-label, dose-escalation study in patients with advanced heart failure caused by ischaemic heart disease in Japan. HS-001 will be transplanted into the diseased tissue of the heart during open-heart surgery. The phase 1/2 study will enrol 10 patients in two dose cohorts of 50 million and 150 million cardiomyocytes. The primary endpoint of the study is safety at 26 weeks post-transplantation, and secondary efficacy endpoints include LVEF and myocardial wall motion.

Filled in by*	Taro Noguchi
Date*	Sep. 19th, 2023