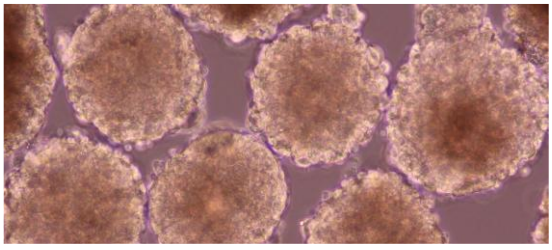
FOR IMMEDIATE RELEASE

Heartseed Announces Enrollment Completion in Phase 1/2 Clinical Trial using HS-001, an Investigational Stem Cell-Derived Therapy for Advanced Heart Failure

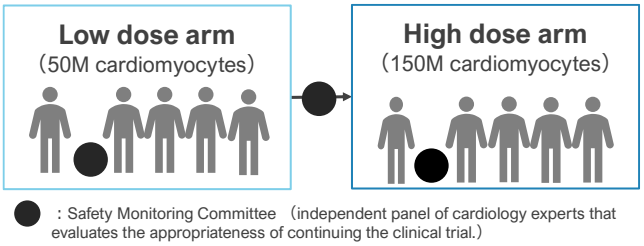
HS-001 consists of clusters of purified heart muscle cells derived from induced pluripotent stem cells (iPSCs).

The clinical phase 1/2 trial (LAPiS Study, NCT04945018) is being conducted in Japan and involves 10 patients with advanced heart failure caused by ischaemic heart disease.

TOKYO, JAPAN, February 3, 2025 – Heartseed Inc. (Headquarters: Minato-ku, Tokyo; CEO: Keiichi Fukuda; hereinafter referred to as "Heartseed") today announced the completion of patient enrollment for the 5th patient in high-dose arm, marking the 10th and final patient enrolled in its Phase I/II clinical trial (LAPiS Study) for HS-001, an allogeneic iPS cell-derived cardiomyocyte spheroid product for advanced heart failure due to ischaemic heart disease.



HS-001 cardiomyocyte drug product



Phased Implementation of the LAPiS Study

As stated in our press release dated October 1, 2024, the Safety Monitoring Committee reviewed the safety data of the first patient in the high-dose cohort (150 million cardiomyocytes) of the LAPiS Study and recommended the continuation of enrollment for the high-dose group. Following this, patient dosing progressed smoothly, and the enrollment of all patients in the LAPiS Study has now been completed.

“We are thrilled to announce the successful completion of patient enrollment in the world's first clinical trial administering cardiomyocyte spheroids. We extend our deepest gratitude to the patients and their families who participated, as well as to the physicians at the medical institutions who carried out the dosing,” said Keiichi Fukuda, CEO of Heartseed. “We will continue to collect data on the efficacy and safety of the LAPiS trial and remain fully committed to expanding treatment options and improving the quality of life for patients."

In 2021, Heartseed and global healthcare company Novo Nordisk signed an exclusive worldwide collaboration and license agreement for development, manufacturing and commercialization of HS-001. Heartseed continues to lead development activities in Japan, while Novo Nordisk has rights to develop and commercialize HS-001 in all other territories.

"Reaching the completion of patient enrollment in the LAPiS clinical trial marks an important milestone. This would not have been possible without the dedication and commitment of the entire Heartseed team. We remain focused on supporting Heartseed's development of HS-001 to address this challenging chronic disease," stated Joachim Fruebis, Corporate Vice President, Cell Therapy R&D, at Novo Nordisk.

About HS-001 and LAPiS Study

HS-001, is an allogeneic iPSC-derived, highly purified ventricular cardiomyocyte product formulated in spheroids. The micro-tissue-like spheroid preparation increases retention rate and viability of the cell graft. The spheroids are transplanted using a special administration needle (SEEDPLANTER®) and guide adapter developed for safe
and efficient administration during open heart surgery.
There are two expected mechanisms of action. Firstly, that the transplanted cardiomyocytes electrically couple with the patient's myocardium, improving cardiac output by remuscularization. Second, that secretion of angiogenic factors from the graft causes new blood vessel development around the transplant site (neovascularization).

The LAPiS Study is a 52-week, phase 1/2, open-label, dose-escalation trial designed to evaluate the safety and efficacy of HS-001 in patients with advanced heart failure caused by ischaemic heart disease. Conducted at multiple sites in Japan, the study has successfully completed enrollment of 10 patients, divided into two cohorts: 5 in the low-dose group (50 million cardiomyocytes) and 5 in the high-dose group (150 million cardiomyocytes). HS-001 was transplanted into the diseased heart during scheduled open-heart surgeries (coronary artery bypass grafting). The primary endpoint of the study is safety at 26 weeks post-transplantation. Secondary efficacy endpoints, assessed at 26 and 52 weeks, include Left Ventricular Ejection Fraction and myocardial wall motion.

About Heartseed

Heartseed Inc. was founded with the aim of realizing cardiac remuscularization therapy, and it was listed on the Tokyo Stock Exchange Growth Market in July 2024 (Stock Code: 219A). Heartseed has proprietary technologies throughout the entire manufacturing process of the cardiomyocyte-cell product, including purification, cell delivery and iPSC production.

This material is intended for global media only.
For journalistic assessment and preparation before publication.

Heartseed announced the global collaboration and license agreement with Novo Nordisk A/S for HS-001 in June 2021. For more information, visit heartseed.jp, LinkedIn and YouTube.

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