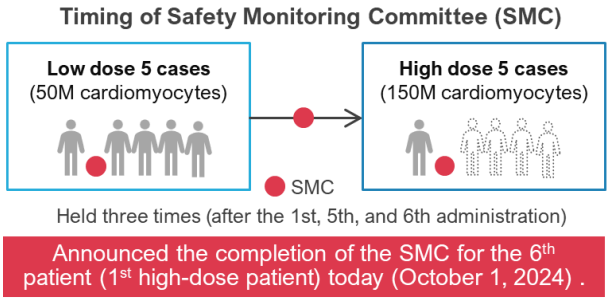
FOR IMMEDIATE RELEASE

Heartseed Announces a Positive Recommendation from the Safety Monitoring Committee for Continuing High-Dose Arm in its Phase 1/2 Clinical Trial using HS-001, an Investigational Stem Cell-Derived Therapy for the Treatment of 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) will enrol 10 patients with advanced heart failure caused by ischaemic heart disease.

TOKYO, JAPAN, October 1, 2024 – Heartseed Inc. (Headquarters: Minato-ku, Tokyo; CEO: Keiichi Fukuda; hereinafter referred to as "Heartseed") today announced that the Safety Monitoring Committee (SMC) has completed its review of the first high-dose patient in the Phase I/II clinical trial (LAPiS Study) for HS-001, an allogeneic iPS cell-derived cardiomyocyte spheroid product for advanced heart failure due to ischemic heart disease. The trial will now continue enrolling the high-dose cohort.



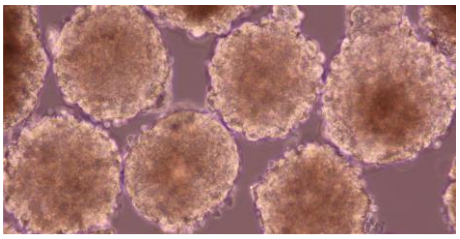
As stated in our press release dated July 30, 2024, the 2nd SMC reviewed the safety results of administering 50 million cardiomyocytes to five patients in the low-dose cohort of the LAPiS trial. Based on their recommendations, initiating the high-dose administration was advised in July 2024. Following this, the first patient in the high-dose cohort was administered in August 2024, and the 3rd SMC assessed the initial safety results, recommending the continuation of the high-dose cohort administration. Heartseed will continue advancing the high-dose cohort administration and the clinical evaluation of HS-001. All three scheduled SMCs for the LAPiS trial was completed. Heartseed plans to enroll additional four patients in the high-dose arm to complete the enrollment in LAPiS Study.

“I am very pleased that we have been able to confirm the initial safety of the high-dose group, in which 150 million cardiomyocytes were administered. I would like to express my heartfelt gratitude to the patients and their families for their cooperation, as well as to the medical professionals who handled the administration,” said Keiichi Fukuda, CEO of Heartseed. “We will continue to steadily advance the LAPiS trial, gathering data on the efficacy and safety of the high-dose group, and will make every effort to expand treatment options and improve the quality of life for patients.”

"We are encouraged by the SMC's recommendation to proceed with the high-dose cohort, as it validates our ongoing efforts to develop innovative therapies aimed at improving the quality of life for patients with advanced heart failure." said 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.



HS-001 cardiomyocyte drug product

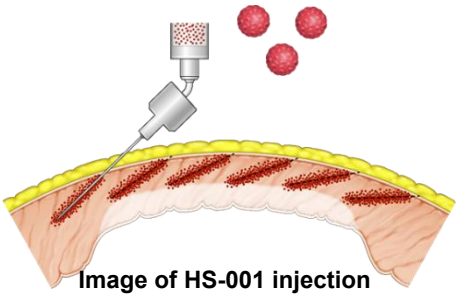


Image of HS-001 injection

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, a 52-week, phase 1/2, open-label, dose-escalation study in patients with advanced heart failure caused by ischaemic heart disease, is being conducted at various sites in Japan. HS-001 will be transplanted into the diseased heart during planned open-heart surgery (coronary artery bypass grafting). The 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. 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.

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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