FOR IMMEDIATE RELEASE

Heartseed Announces a Positive Recommendation from the Safety Monitoring Committee for Dose Escalation 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.

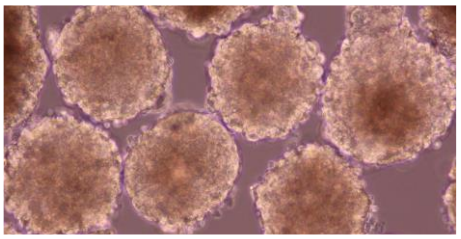
TOKYO, JAPAN, July 30, 2024 – Heartseed Inc. (Headquarters: Minato-ku, Tokyo; CEO: Keiichi Fukuda; hereinafter referred to as "Heartseed") today announced that the Safety Monitoring Committee (SMC) has completed its review of the low-dose patient cohort in the Phase I/II clinical trial (LAPiS Study) for HS-001, an allogeneic iPS cell-derived cardiomyocyte spheroid product for advanced heart failure due to ischemic heart disease. The trial will now enrol the high-dose cohort.

The ongoing Phase I/II LAPiS trial is designed to evaluate the safety and tolerability of HS-001 in patients with advanced heart failure. The administration to five patients in the low-dose (50 million cardiomyocytes each) cohort was completed in May 2024. No dose-limiting toxicities or safety concerns affecting the continuation of the trial have been observed. The Safety Monitoring Committee (SMC) reviewed the safety data collected thus far and recommended proceeding to the high-dose cohort of 150 million cardiomyocytes. Heartseed plans to start the high-dose administration to continue the clinical evaluation of HS-001.

“Obtaining approval to initiate the high-dose cohort is a significant milestone for HS-001. This will allow us to gather more comprehensive data on the efficacy and safety of our therapy, bringing new hope to patients with advanced heart failure,” said Keiichi Fukuda, CEO of Heartseed. “We are pleased with the continued interest in our therapy and look forward to further enrollment in the LAPiS Study. We are committed to expanding treatment options and improving the quality of life for our patients.”

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



HS-001 cardiomyocyte drug product

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).

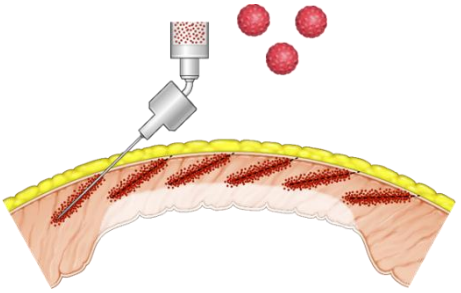


Image of HS-001 injection

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 in 2015 to develop and commercialize cardiac remuscularization therapy developed by Professor Keiichi Fukuda and his group at the Department of Cardiology, Keio University, Tokyo, Japan. 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. Heartseed received "Minister of Science and Technology Policy Award" at Japan Venture Awards 2021 and "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. For more information, visit heartseed.jp, LinkedIn and YouTube.

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