

FOR IMMEDIATE RELEASE

Heartseed Announces Acceptance by PMDA of Clinical Trial Notification of LAPiS Study, a Phase I/II Clinical Trial of HS-001, iPSC-derived Cardiomyocyte Spheroids for Heart Failure in Japan

TOKYO, JAPAN, March 22, 2021 – Heartseed Inc. (hereinafter Heartseed), a Tokyo-based biotechnology company developing iPSC-derived cardiomyocyte spheroids for the treatment of heart failure (hereinafter HF), today announced the successful completion of Japan's Pharmaceutical and Medical Devices Agency (PMDA) review of the Clinical Trial Notification (CTN), allowing the commencement of a Phase I/II clinical trial (LAPiS Study) evaluating the safety and efficacy of HS-001, for the treatment of HF caused by ischemic heart disease in Japan.

About heart failure

Heart failure is a condition in which the heart's pumping function (the ability to pump blood throughout the body) is impaired due to ischemic heart disease such as myocardial infarction or dilated cardiomyopathy. It is estimated that 1.2 million people in Japan and 26 million people in the world suffer from heart failure, and the number of patients continues to increase, called a "heart failure pandemic. Heart disease, including heart failure, is the second leading cause of death in Japan after cancer, and the leading cause of death in the world. Despite recent advances in treatment, patients with severe heart failure have no curative treatment options other than heart transplantation, and there is a need to develop innovative heart failure treatments.

About HS-001

Heartseed's lead pipeline, HS-001, is allogeneic iPSC-derived, highly purified ventricular cardiomyocyte spheroids. By forming micro-tissue like spheroids, retention rate and viability are improved. The spheroids are transplanted using a special administration needle (SEEDPLANTER®) and guide adapter developed for the safe and efficient administration 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 generate contractile force (remuscularization), and the transplanted cells secrete angiogenic factors to form new blood vessels around the transplant site (neovascularization).

About the LAPiS Study (Phase I/II)

Heartseed has been in discussions with the Pharmaceuticals and Medical Devices Agency (PMDA) to conduct a Phase I/II study (LAPiS Study) of HS-001, and submitted a clinical trial notification in February 2021, and its review period was completed.

The LAPiS Study will evaluate the efficacy and safety of HS-001 implantation and the efficacy and safety of tacrolimus tablets^{*1} used in combination with HS-001 implantation in patients with severe heart failure associated with ischemic heart disease.

*1: tacrolimus tablets: Because of the possibility of an immune reaction after cell transplantation, tacrolimus tablets (provided by Towa Pharmaceutical Co., Ltd.), which have already been clinically proven in organ transplantation, etc., will be used as an immunosuppressive agent in this clinical trial.

About Heartseed

Heartseed Inc. was founded in 2015 to develop and commercialize cardiac regenerative medicine developed by Prof. Keiichi Fukuda and his group at the Department of Cardiology, Keio University, Tokyo. Heartseed has original technologies throughout the process of manufacturing and delivering iPSC-derived cardiac regenerative medicine, including purification, cell delivery and iPSC production, and has raised more than USD 38 million. Heartseed is also supporting an investigator-initiated clinical trial for HF (IPSCS Study) at Keio University, Japan. <https://jrct.niph.go.jp/en/latest-detail/jRCTa032200189>

Company Name: Heartseed Inc.
Established: November 30, 2015
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SBI Investment, JMDC, Gene Techno Science, Nissay Capital, SMBC Venture Capital
Website: <http://www.heartseed.jp/en/index.html>
Awards: Minister of Science and Technology Policy Award (Japan Venture Awards 2021)
Healthcare Company of the Year 2020 (Healthcare Insights)

Source: Heartseed Inc.

For more information on Heartseed, please visit <http://www.heartseed.jp/en/index.html>

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