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Notice Regarding the New Partner for Delivery Catheter System for Allogeneic iPS Cell-Derived Cardiomyocyte Spheroids

- The two companies will combine their strengths and collaborate toward a clinical trial for minimally invasive cardiac regeneration therapy.

TOKYO, JAPAN, September 11, 2025 - Heartseed Inc. (Headquarters: Minato-ku, Tokyo; CEO: Keiichi Fukuda; hereinafter referred to as “Heartseed”) and Japan Lifeline Co., Ltd. (Headquarters: Shinagawa-ku, Tokyo; President and CEO: Keisuke Suzuki; hereinafter referred to as “Japan Lifeline”) are pleased to announce that the collaboration and partnership regarding the clinical trial of Heartseed’s allogeneic iPS cell-derived cardiomyocyte spheroids “HS-005” is progressing smoothly. Heartseed will use the delivery catheter system from Japan Lifeline for this clinical trial and proceed with the patient recruitment. The goal of submitting the clinical trial application by the end of 2025 remains unchanged.

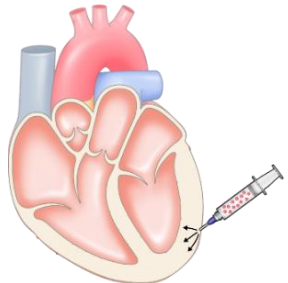
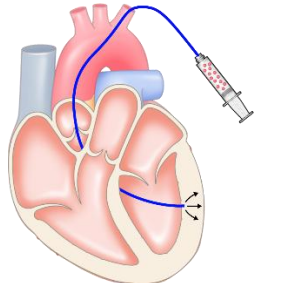
While the lead pipeline HS-001, which has completed patient enrollment in the domestic LAPiS trial and is currently under follow-up observation, administers allogeneic iPS cell-derived cardiomyocyte spheroids to patient hearts intramyocardially via open-heart surgery, the next generation pipeline HS-005 administers the cardiomyocyte spheroids into myocardial wall by delivery catheter system incorporating Japan Lifeline's manufacturing expertise in cardiac catheters.

【About HS-005】

The cell utilized by Heartseed in cardiac remuscularization therapy is an allogeneic iPSC-derived, highly purified ventricular cardiomyocyte product formulated in spheroids. The non-clinical studies confirmed that forming micro-tissue-like spheroids enhances the cell retention rate and viability compared to single cells in their administration.

When administering cardiomyocyte spheroids into the myocardial layer of the heart, HS-001 uses a proprietary delivery needle (SEEDPLANTER®) and guide adapter developed in-house for epicardial delivery. In contrast, HS-005 utilizes a catheter system for endocardial delivery.

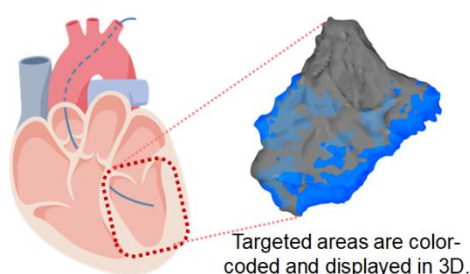
The administered cardiomyocytes are expected to be engrafted into the patient's myocardium, promoting “remuscularization” and improving cardiac contractility. Additionally, they are anticipated to secrete various angiogenic factors, promoting neovascularization (formation of new blood vessels) around the administration sites.

HS-001 (Administering the cells from outer surface of the heart)	HS-005 (Administering the cells from inside of the heart)
 <p>Open chest surgery required</p>	 <p>Open chest surgery not required</p>

Japan Lifeline is a medical device manufacturer boasting the top market share in diagnostic catheters for arrhythmia. The company is also the only one in Japan with experience developing cardiac cell delivery catheters that have been used in clinical trials for human dosing.

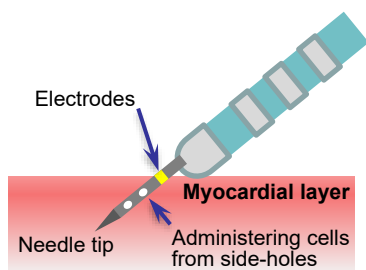
The delivery catheter system provided by Japan Lifeline features mechanisms for the precise delivery of cells to targeted sites. The catheter is compatible with 3D mapping systems, allowing physicians to manipulate the catheters to the intended location inside the heart while viewing the heart's chamber anatomical image. Furthermore, its unique structure featuring electrodes at the tip of the catheter allows for administering the cells while confirming via ECG changes indicating the tip has reached the myocardial layer.

【About 3D mapping function】



3D mapping is a technology that enables three-dimensional visualization of the electrical signals and structures within the heart. In arrhythmia treatment, it has contributed to improving treatment accuracy by precisely identifying the source of abnormal electrical signals and the shape of the heart chambers. By applying this technology to

cardiac remuscularization therapy, the companies aim to enhance the precision of cell delivery to the targeted sites.



ECG responses when the electrodes arrive at myocardial layer

“To transplant iPS cell-derived cardiomyocytes into the myocardial wall via catheter, a system is required that can identify the targeted sites and safely and accurately deliver the catheter tip there. Japan Lifeline possesses the advanced technology and extensive experience to make this possible. We consider this a major step forward toward the societal implementation of this minimally invasive cardiac remuscularization therapy.”, said Keiichi Fukuda, CEO of Heartseed.

Additionally, Keisuke Suzuki, President and CEO of Japan Lifeline, stated: “Contributing to regenerative medicine is our long-cherished aspiration. We are delighted that our high-functional catheters will support Heartseed's innovative treatment. By combining the strengths of both companies, we will strive to deliver new hope to patients suffering from heart failure.”

Heartseed and Japan Lifeline will dedicate their full efforts to rapidly and reliably advancing minimally invasive cardiac remuscularization therapy through this partnership.

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](#).

About Japan Lifeline

Japan Lifeline Co., Ltd. (Tokyo Stock Exchange Prime Market: 7575) is a medical device company specializing in the cardiac and cardiovascular fields. The company focuses primarily on electrophysiology catheters and vascular grafts. It builds its product portfolio through distribution operations that introduce superior overseas medical devices to Japan. The company also develops and produces proprietary products through its manufacturing capabilities. Operating through 48 domestic sales offices while expanding its proprietary products globally, Japan Lifeline provides the latest and most suitable medical devices to healthcare professionals and patients worldwide. For more information, visit <https://www.jll.co.jp/>.

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