HEARTSEED INC.

Breakthrough cell therapy for severe heart failure using regenerated cardiomyocytes obtained from iPSC (induced Pluripotent Stem Cells)

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Japan

https://heartseed.jp

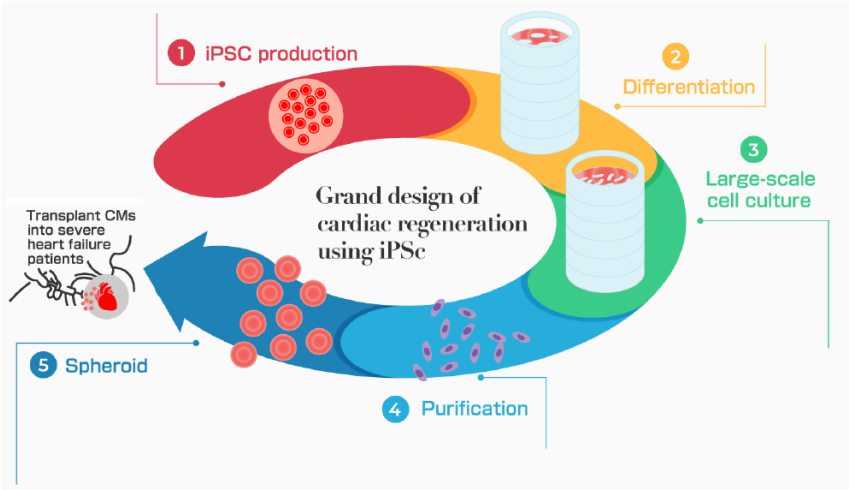
Founded 2015
Founder & CEO: FUKUDA Keiichi, MD/PhD
No. of employees: 40
Type of Ownership: Private
Primary stock exchange: N/A

December 2021: As an innovative new treatment option for heart failure, a unique cardiac remuscularization therapy has been invented by Dr. FUKUDA Keiichi, Founder & CEO, Professor at Keio University School of Medicine.

Venture Valuation (VV) interviewed YASUI Kikuo, COO.

VV: **Heartseed is going to start Phase I/II clinical studies in Japan for your lead asset HS-001, cell therapy with allogenic iPSC-derived highly purified ventricular cardiomyocyte spheroids. It can be a registrational trial under an accelerated approval scheme.**

Yasui: HS-001 is to focus on treatment for HFrEF (Heart Failure with reduced Ejection Fraction) generally affected by myocardial infarction (ischemic) and cardiomyopathies (non-ischemic).



Our proprietary differentiation and purification processes eliminate undifferentiated cells and non-cardiomyocytes. In doing so, the risk of arrhythmia and teratoma formation is dramatically reduced.

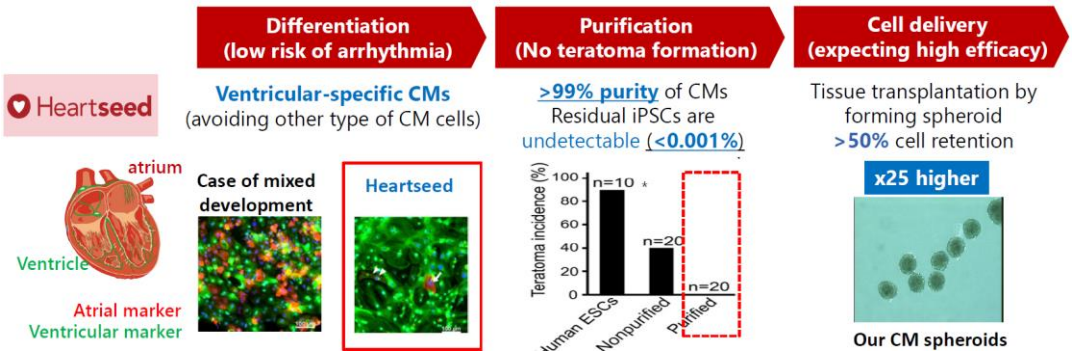
A considerable quantity of cardiomyocytes is necessary for cardiac regenerative medicine. Therefore, we invented large-scale cell culture technology.

We have also developed a method for efficient transplantation by creating a cardiomyocyte spheroid (around 150μ in diameter), in which about 1,000 cardiomyocytes are aggregated and transplanted into the heart tissue.

By means of micro-tissue-like spheroids, the retention rate and viability of cell transplants are substantially improved. The spheroids are transplanted using a special administration needle SEEDPLANTER® for efficient engraftment. Cardiomyocytes are expected to be electronically connected with patient's heart to improve cardiac output by remuscularization and form new blood vessels around the transplant site.

VV: **You possess a robust patent portfolio for the entire production process of cardiomyocytes, differentiation, purification, large scale cell culture, and cell delivery system technologies.**

Yasui: As described in this image, multiple technologies are needed to make cardiac regenerative medicine happen. We have developed oiriginal technologies across the steps and our patent portfolio and knowhow covers differentiation, purification, large scale cell culture, and cell delivery.



VV: **In order to accelerate HS-001 product development and international marketing, your recent collaboration and license agreement with Novo Nordisk, a top global pharmaceutical company, is a considerable advantage. Are you thinking about other partners in the future?**

Yasui: As a startup company with unprecedented technology, we are thrilled to have a top multinational pharmaceutical company such as Novo Nordisk as our partner.

In addition to HS-001, we are working on other projects for which partnership opportunities remain. For instance, we are in the process of developing autologous cell therapy and catheter to transplant cardiomyocyte spheroids by minimally invasive procedures, and so on.

For further company's growth, we are also wishing to interest international investors.

VV Comments after the interview:

Science Daily on February 11, 2021 published an article titled "Heart failure cases soar globally"[1]. The article asserts that "the number of patients with heart failure worldwide nearly doubled from 33.5 million in 1990 to 64.3 million in 2017" based on a study in the European Journal of Preventive Cardiology, a journal of the European Society of Cardiology.

The American Heart Association Report – Annual Statistical Update published January 27, 2021[2] mentions "Heart disease remains the #1 cause of death worldwide". The report also points out that "the effects of COVID-19 are likely to influence cardiovascular health and mortality rates for many years, directly and as a result of increased lifestyle-related risks during and after the pandemic."

Patients with severe heart failure have few surgical options: primarily CRT-D (Cardiac Resynchronization Therapy Defibrillator), and LVAD (Left Ventricular Assist Device). As a totally different alternative, the cell therapy that Heartseed has invented will provide a paradigm shift in treating severe heart failure and improving patient's quality of life and well-being.

Contact

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Venture Valuation specializes in independent assessment and valuation of technology-driven companies in growth industries, such as the Life Sciences (Biotech, Pharma, and Medtech), ICT, Femtech, Nanotech, Cleantech and Renewable Energy. In addition to valuation products, Venture Valuation offers high-quality, focused information services like the Global Life Sciences Database, Biotechgate.com and this *"Let's Interview Series"* with companies with interesting technologies and services. We select and interview thriving companies and organizations especially in Switzerland and Japan.

[1] https://www.sciencedaily.com/releases/2021/02/210211195326.htm
[2] https://newsroom.heart.org/news/heart-disease