

This material is intended for global medical media only.
For journalistic assessment and preparation before publication.

press release

Heartseed and Novo Nordisk enter into global collaboration and licence agreement for stem cell-based therapy for heart failure

Bagsværd, Denmark and Tokyo, Japan, 1 June 2021 – Heartseed Inc. and Novo Nordisk A/S today announced that they have entered into an exclusive worldwide collaboration and licence agreement for development, manufacturing and commercialisation of Heartseed’s lead asset HS-001.

HS-001 is an investigational cell therapy using purified cardiomyocytes derived from induced pluripotent stem cells (iPSC), which is currently under development by Heartseed for the treatment of heart failure.

Heartseed is planning to initiate a phase 1/2 clinical trial in Japan (LAPiS Study) in the second half of 2021 evaluating the safety and efficacy of HS-001 for the treatment of heart failure caused by ischemic heart disease. Japan’s Pharmaceutical and Medical Devices Agency has approved Heartseed’s Clinical Trial Application to carry out the clinical trial.

Under the terms of the agreement, Novo Nordisk gains exclusive rights to develop, manufacture and commercialise HS-001 worldwide except in Japan. Heartseed will maintain the rights to solely develop HS-001 in Japan and Novo Nordisk has the rights to co-commercialise the product in Japan with Heartseed with 50/50 profit and cost sharing.

Heartseed is eligible to receive payments totalling up to 598 million US dollars including 55 million dollars in upfront and near-term milestone payments. Heartseed is also eligible to receive tiered high single-digit to low double-digit royalties of annual net sales outside of Japan.

"We are delighted to have a company with the expertise and resources of Novo Nordisk as our partner for development and commercialisation of HS-001, and are also honoured that Novo Nordisk has recognised the innovativeness and high potential of our technology," said Keiichi Fukuda, CEO of Heartseed. "We believe that the partnership with Novo Nordisk is very valuable as we seek to disseminate our Japan-origin innovation globally as early as possible."

"Through this important collaboration with Heartseed, we aim to pioneer novel treatment solutions for people with cardiovascular disease. We gain access to an innovative clinical asset, underlying technology and deep expertise within the field of iPSC biology and cardiac cell transplantation, which can be combined with our knowledge and capabilities in stem cell biology and manufacturing," said Marcus Schindler, chief scientific officer, EVP Research and Early Development at Novo Nordisk. "Novo Nordisk Stem Cell R&D is uniquely placed to accelerate the development of this potential therapy, and this exciting deal fits with our increased focus on cardiovascular disease which is the world's leading cause of death."

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 of cell transplant are improved. The spheroids are transplanted using a special administration needle (SEEDPLANTER®) and guide adapter developed for the administration of the spheroids 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 improve cardiac output by remuscularisation, and secretion of angiogenic factors to form new blood vessels around the transplant site (neovascularisation). The review of the Clinical Trial Application of a phase I/II clinical trial (LAPiS Study) evaluating the safety and efficacy of HS-001 for the treatment of heart failure caused by ischemic heart disease in Japan was successfully completed in March 2021 by Japan's Pharmaceutical and Medical Devices Agency.

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 was named "Healthcare Company of the Year 2020" by Healthcare Magazine and "Top 10 Startup in Japan" by Startup City and "Minister of Science and Technology Policy Award" at Japan Venture Awards 2021. For more information, visit [LinkedIn](#).

About Novo Nordisk

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 45,800 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, [Facebook](#), [Twitter](#), [LinkedIn](#), [YouTube](#).

Further information

Heartseed Inc:

Kikuo Yasui, COO

+81 3 6380 1068

kikuo.yasui@heartseed.jp

Novo Nordisk, Media:

Mette Kruse Danielsen

+45 3079 3883

mkd@novonordisk.com

Michael Bachner (US)

+1 609 664 7308

mzyb@novonordisk.com

Novo Nordisk, Investors:

Daniel Muusmann Bohsen

+45 3075 2175

dabo@novonordisk.com

Ann Søndermølle Rendbæk

+45 3075 2253

arnd@novonordisk.com

David Heiberg Landsted

+45 3077 6915

dhel@novonordisk.com

Mark Joseph Root (US)

+1 848 213 3219

mjhr@novonordisk.com