

World Premiere in the Treatment of Advanced Heart Failure

FineHeart Announces Success of the First Stage of Its "First in Human" Clinical Study

The results were presented at the 8th EACTS summit *European Association for Cardiac and Thoracic Surgery*

Bordeaux, France, November 12, 2024 – FineHeart, a clinical-stage MedTech company developing innovative medical devices for heart failure, has achieved a major milestone in its "First in Human" study, clinically confirming the proof of concept for FlowMaker®.

The device was implanted in patients for the first time on a beating heart, without an intensive cardiac arrest procedure, thereby reducing surgical risks and improving the patients' recovery. The procedure was performed using a new minimally invasive technique, allowing FlowMaker® to synchronize its operation with the natural contractions of the heart, and optimize blood flow without requiring an external bypass, unlike all other devices.

Due to its compact size and low energy consumption, the fully implanted FlowMaker® benefits from wireless power supply, which represents a significant and unparalleled progress for patients awaiting long-term hemodynamic support.

These implantations are part of a "First in Human" European study conducted by Professor Ivan Netuka, MD, Principal Investigator, Head of the Department of Cardiovascular Surgery, and his team at the IKEM (Prague), a center of excellence for cardiovascular research.

The first results were presented by Professor Netuka during a plenary session specifically dedicated to clinical studies on Friday, November 8, 2024, at the 8th International Summit on Mechanical Circulatory Support organized by EACTS, the European Association for Cardiac and Thoracic Surgery.

The FineHeart Research and Development team would like to offer their sincere thanks to Professor Ivan Netuka for his leadership and vital contribution throughout this project. The team said "This success is the result of a close collaboration and the commitment of the entire team".

Arnaud Mascarell, CEO and co-founder of FineHeart, underlines the importance of this milestone for the company's development: "This crucial achievement allows us to realize FineHeart's vision. The results observed provide promising insights into what we can offer patients and pave the way for international multicenter trials aimed at confirming these results on patients over longer periods."

Dr. Stéphane Garrigue, MD, PhD, CSO and co-founder of FineHeart, adds: "The results observed in particularly vulnerable patients confirm the potential that FineHeart had already identified in numerous preclinical studies. This first stage of the 'First in Human' study marks a significant step towards effective wireless therapy that is more physiological, less invasive, and better adapted than existing treatments."

Professor Laurent Barandon, MD, PhD, cardiac surgeon in Bordeaux and surgical team trainer for FlowMaker® implantation, concludes: "The surgical tools developed by FineHeart for this pilot study were successfully implemented by the Prague team, demonstrating the feasibility of this new minimally invasive operative procedure. The capacity of this fully implantable wireless medical device to support the natural cardiac function could expand therapeutic options for many patients with less severe forms of the disease."

About FLOWMAKER® is the first implantable cardiac output accelerator, designed by French electrophysiologists and rhythmologists. Fully intraventricular, it provides physiological support synchronized with the natural heart contractions. It respects natural blood flow and does not require aortic bypass, unlike other devices. It is the first miniaturized device – only 10 cm – that adapts to patients' needs like a pacemaker, allowing targeted treatment based on the severity and progression of the disease. Completely implanted in the patient's body, it has no external power cables as it is recharged via a transcutaneous energy transfer (TET) system, thereby avoiding any risk of infection and significantly improving patients' quality of life. The device is implanted through a minimally invasive procedure on a beating heart, with an average duration of 90 minutes. Thanks to its unique features, FLOWMAKER® represents an effective and highly promising therapeutic alternative for over 200,000 patients per year suffering from severe heart failure who cannot benefit from current therapeutic solutions.

About IKEM - IKEM - Institute of Clinical and Experimental Medicine IKEM - the Institute of Experimental and Clinical Medicine - is the largest clinical and medical research hospital in the Czech Republic. Managed directly by the Ministry of Health since its founding in 1971, it specializes in treating cardiovascular diseases, organ transplantation, diabetology, and metabolic disorders. Based in Prague, IKEM is one of Europe's leading organ transplantation centers. Its work attracts researchers, educators, and clinicians from around the world.

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About FineHeart - [FineHeart](#)

FineHeart is a Bordeaux-based medical device company at the clinical stage. Its innovative product, FLOWMAKER®, could treat 200,000 patients with severe heart failure every year. FineHeart is initially targeting the 50,000 most severe patients eligible for cardiac assistance, but not treated by current LVADs. This first potential market is estimated at over US\$5 billion.

FineHeart was founded by CEO Arnaud Mascarell and a team of internationally renowned cardiac surgeons and electro-physiologists, including Dr. Stéphane Garrigue, CSO and inventor of the concept, and Dr. Philippe Ritter, co-inventor of cardiac resynchronization therapy (CRT). The company holds an international portfolio of 147 patents in 25 different families.

FineHeart benefits from the support of a wide range of public, private, industrial and independent investors: including the French groups Lauak and Doliam, FineHeart Founders, as well as the investment funds and historical shareholders Aquiti, Broadview Ventures, Galia, Irdi, M Capital, NACO, UI Investment, Verve Ventures. FineHeart is also financed by the European Union (EIC), Bpifrance and the Nouvelle Aquitaine and Région Centre regions.

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