FineHeart
A healthier life with every beat

Press release

FineHeart receives ANSM[1] authorization to deploy its *First-In-Human* clinical study in France

Patients with advanced heart failure will be treated with FlowMaker®, an innovative, fully implantable device for restoring cardiac output.

Bordeaux, France - June 3, 2025 - FineHeart S.A., a clinical-stage medical technology company specializing in the development of innovative solutions for cardiology, announces that it has received authorization from the French National Agency for the Safety of Medicines and Health Products (ANSM) to initiate its *First-In-Human* (FIH) clinical trial in France.

This prospective, non-randomized study is designed to assess the safety, implant feasibility and preliminary clinical performance of the FlowMaker® device in patients with advanced heart failure. It follows the first successful implantations carried out in 2024 at IKEM (*Institute for Clinical and Experimental Medicine*) in Prague, whose initial results have been presented at several international scientific congresses.

Conducted in several French centers specializing in cardiac surgery, this study represents a decisive step in the clinical development of FlowMaker®.

FlowMaker® is a new-generation, fully implantable left ventricular assist device designed to work in synergy with the heart's natural contraction. Less invasive than current devices, this technology aims to preserve native cardiac function while significantly improving patients' quality of life.

Pr Pascal Leprince, **Head of the Thoracic and Cardiovascular Surgery Department at Hôpital Universitaire Pitié-Salpêtrière (AP-HP) Sorbonne Université and principal investigator of the clinical trial in France,** commented: "*The launch of this trial in France represents a highly promising step forward for patients with advanced heart failure. Thanks to its pulsatile operation, synchronized with the heart's electrical activity, the FlowMaker® could transform the treatment of these patients, offering them a less invasive and potentially more durable solution than current devices. We look forward to starting this clinical study and confirming these benefits*."

"ANSM approval marks a key strategic step for FineHeart. It validates the quality and solidity of our preclinical work and confirms the relevance of our initial clinical results. This green light paves the way for the acceleration of our clinical roadmap, with the ambition of responding to a major unmet medical need. It also sends a strong signal to the entire MedTech ecosystem, and to all our partners and investors, whom we thank for their confidence" says **Arnaud Mascarell, CEO and co-founder of FineHeart.**

[1] ANSM: French National Agency for the Safety of Medicines and Health Products

About FlowMaker®

FlowMaker® is the first implantable cardiac output accelerator, designed by French electrophysiologists and rhythmologists. It assists the heart, adapts to the evolution of the pathology, and can be simply removed without critical risk to the patient. Fully intraventricular, it provides physiological support synchronized with the natural heart contractions. It respects natural blood flow and does not require aortic bypass. By operating in synergy with the native cardiac contraction, the FlowMaker® consumes little energy and does not require any percutaneous connection to external batteries. 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. This procedure is widely practiced by cardiac surgeons and limits any physiological changes. FlowMaker® represents an effective therapeutic alternative for more than 200,000 patients per year suffering from advanced heart failure who cannot benefit from current therapeutic solutions.

About FineHeart - FineHeart

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

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.

Financed by a consortium of public and private investors, including the founders' holding company, FH Founders, and the Lauak and Doliam industrial groups, FineHeart is supported by the European Union (EIC), Bpifrance and the Nouvelle-Aquitaine and Centre-Val de Loire regions.

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