

## FineHeart receives Slovenia JAZMP<sup>1</sup> authorization to launch its FIH clinical study on patients suffering from advanced heart failure

<sup>1</sup>*Agency for Medicinal Products and Medical Devices of the Republic of Slovenia*

**Bordeaux, France – Ljubljana, Slovenia, July 1st 2025** - a clinical-stage medical technology company specializing in the development of innovative solutions for cardiology, announces that it has received authorization from JAZMP, the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, to begin its First-In-Human (FIH) clinical study.

This prospective, non-randomized study is designed to assess the safety, implant feasibility and preliminary clinical performance of the FlowMaker<sup>®</sup> device in patients with advanced heart failure.

FlowMaker<sup>®</sup> 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.

**Professor Ivan Knežević, MD.PhD, cardio surgeon and director of the Transplantation Centre of the University Medical Centre in Ljubljana**, will lead the study. *"It is a real privilege to take part in this first FIH study. FlowMaker represents a major technological advance in the treatment of patients with advanced heart failure"* he said.

**Arnaud Mascarell, CEO and co-founder of FineHeart**, comments: *"Following approvals in the Czech Republic and France, the Slovenian authorization represents another strong endorsement of our preliminary clinical results and our technology by European health authorities. It reflects the growing confidence within the cardiology community in our disruptive approach. This latest green light reinforces our clinical strategy across Europe—a critical step toward securing CE marking. Our goal remains clear: to deliver an innovative, less invasive solution for patients with advanced heart failure, where current treatment options remain limited."*

### About FlowMaker<sup>®</sup>

**FlowMaker<sup>®</sup>** 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<sup>®</sup> 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<sup>®</sup>

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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