



Press release

FineHeart named leader of the IPCEI Health Tech4Cure to spearhead the structuring of the European implantable medical device sector

Bordeaux, France – July 24th 2025 – FineHeart, a clinical-stage medical technology company specializing in the development of innovative solutions for cardiology, has been designated as the lead partner of the IPCEI *Tech4Cure* (Important Project of Common European Interest), dedicated to the implantable medical device (IMD) sector. This project isjointly notified by six EU Member States – France, Hungary, Italy, Latvia, Slovakia, and Slovenia - .

FineHeart will carry out its *SmartDMIA* program to structure the innovative active implantable medical device (AIMD) sector, which is essential for public health and Europe's industrial autonomy, in synergy with other European laureates of the *Tech4Cure* program.

Arnaud Mascarell, CEO and co-founder of FineHeart, said: "Being named leader of the IPCEI Tech4Cure with our SmartDMIA project is a source of immense pride. It is the recognition of our innovation ability and our technological and industrial leadership. This project will strengthen our sustainable growth and increase our international visibility. Together with our academic and industrial partners, we will build a sovereign, competitive and sustainable AIMD industry serving the health of European citizens."

The *SmartDMIA* project will cover the entire value chain—from design to industrialization—of nextgeneration active implantable medical devices (AIMDs), for which energy supply is a major technological and medical challenge. The main development areas are:

- Extending the lifespan of encapsulated electronic components, enabling the integration of miniaturized transcutaneous energy and data transfer systems
- **Developing universal interoperability between devices**, regardless of their power (from a few milliwatts to 30 W), to optimize energy management and diagnostics and promote personalized medicine (5P medicine)
- Harmonization of standards for communication, cybersecurity, and interconnection with hospital systems and digital platforms.

FineHeart will leverage its R&D know-how perfected during the development of **FlowMaker®**, the world's first and only miniaturized, fully implantable, wireless cardiac flow accelerator with no external battery for the treatment of advanced heart failure. This breakthrough device, currently in European clinical trials, adapts to the progression of the disease and provides physiological support synchronized with the heart's natural contractions.

Through this pioneering role, FineHeart has become a strategic player in the transformation of the European AIMD sector contributing its expertise and supporting European industrial competitiveness.

About the **PIIEC**

Launched by France in 2022, the PIIEC Santé aims to create a "Europe of Health" by promoting the emergence of European champions in disruptive technologies in the sector. This initiative aims to strengthen European production capacities in the health field, while stimulating the formation of ambitious European partnerships around innovative projects, thus ensuring European sovereignty.

Coordinated by the Directorate-General for Enterprise (DGE), this project is being rolled out in two complementary waves: the first, authorized on May 28, 2024, targets essential medicines and critical molecules (Med4Cure); the second, entitled Tech4Cure, is dedicated to innovative MedTech medical devices (Tech4Cure

Tech4Cure aims to establish projects at European level focusing on:

- The lifespan of active implantable medical devices, in particular the lifespan of batteries and any components, materials, and technologies designed to extend the lifespan of active implantable medical devices, thereby promoting the digital and ecological transition.
- Connected and portable medical imaging solutions to promote more compact imaging devices, harnessing the potential of AI and IoT to facilitate remote examinations and increase the pool of available equipment.
- Sustainable design of medical devices, by strengthening the ecological transition in the design of medical devices, in particular through the use of biomaterials and eco-design to stimulate innovation in raw material supply and sustainability.

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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