

Treatment of severe heart failure - AI

**FineHeart reinforces its industrial credentials and long-term strategy by adding manufacturing to its ISO 13485: 2016 certification**

**Bordeaux, France, February 12, 2025** - FineHeart S.A., a clinical-stage medtech company developing breakthrough solutions for cardiology, announces the extension of its ISO 13485:2016 certification to cover all processes related to the production of its fully implantable cardiac assist device, the FlowMaker®.

Issued following an audit conducted by BSI, an independent notified body of international reference, this certification validates the robustness of the quality management system implemented by the company over the last 10 years. Hitherto limited to R&D activities, the extension of ISO 13485:2016 certification to manufacturing is **an essential milestone in FineHeart's industrialization phase and reinforces its long-term strategy.**

**Arnaud Mascarell, CEO and co-founder of FineHeart, commented:** *"This new certification illustrates the maturity of our quality management and the reliability of our industrial processes, which will be deployed at our future production site. The new manufacturing facility and head office, which is currently under construction near Bordeaux, will centralize research and development, performance testing and all the industrial processes needed to produce the FlowMaker® for future commercial supply."*

**Sophie Jonquière, Purchasing and Supply Chain Director, comments:** *"The extension of our ISO 13485:2016 certification demonstrates FineHeart's ability to ensure a reliable supply chain and to implement a unique industrial tool at the service of its breakthrough technology. It validates the robustness of our FlowMaker® manufacturing processes, which meet the highest standards of sanitary quality, notably for our clinical trials currently underway in Europe, and future CE marking and PMA studies in the United States."*

**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 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. The first two patients have been implanted successfully as part of the European FIH (First In Human) trials. Further European cardiology centers are expected to join the trials shortly, including France.

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.

## **Contact**

### **Europe**

#### **Media Relations**

Annie-Florence Loyer  
afloyer@newcap.fr  
+33 (0) 6 88 20 3559

### **FineHeart Communication**

James Palmer  
[james.palmer@fine-  
heart.com](mailto:james.palmer@fine-heart.com)  
+33 (0) 7 60 92 77 72