

## FineHeart obtains Czech health authority approval to commence First in Human clinical study

*Severe Heart Failure patients to be treated with the FLOWMAKER®, FineHeart's fully implantable breakthrough innovation to restore cardiac output.*

**Bordeaux, France, October 3, 2023** - FineHeart S.A, a medical device company developing innovative devices for cardiology announced today that it has received authorization from the SUKL (the Czech Republic State Institute for the Control of Medicinal Products) to carry out *"A prospective, single arm, single center, First in Human Study to evaluate the safety and performance at 30 days of the FineHeart FLOWMAKER® in subjects with advanced heart failure."*

This first trial will be carried out at the IKEM in Prague (The Institute for Clinical and Experimental Medicine), one of Europe's leading centers of excellence for cardiac research, heart transplants, and LVAD implantation (Left Ventricular Assist Device).

"This authorization marks a major milestone in the development of FineHeart. It results from many years of hard work by our teams and partners, as well as our investors' loyal and unrelenting support. Reaching this point reflects our unwavering commitment to push forward the boundaries of medical device technology to bring hope to patients suffering from severe heart failure. This new treatment is designed to help patients regain their independence and improve their quality of life." **declared Arnaud Mascarell, CEO & co-founder of FineHeart.**

"We are delighted to start our clinical program with the team of Professor Ivan Netuka, Chair of the Cardiovascular Surgery Department at IKEM. He will serve as the trial's principal investigator. Thanks to his department's unique expertise in international innovative clinical studies and conventional LVAD therapy, the medical team will be able to demonstrate the ease and short implantation procedure of the FLOWMAKER® in a beating heart. Given the device's unique features it aims to significantly reduce the complications observed with LVADs." **said cardiologist Dr. Stephane Garrigue, the inventor of the FLOWMAKER® and CSO of FineHeart.**

### **About IKEM - [IKEM - Institut Klinické a Experimentální Medicíny](#)**

IKEM - Institute of Experimental and Clinical Medicine - is the largest clinical and research hospital Czech medical. Directly managed by the Ministry of Health since its creation in 1971, it is specialized in the treatment of cardiovascular diseases, organ transplantation, diabetology or metabolic disorders. Based in Prague, IKEM is one of the largest transplant centres of European bodies. His work attracts researchers, educators and clinicians from around the world.

### **About The FLOWMAKER®**

The FLOWMAKER® is the first fully intraventricular, wireless flow accelerator that provides physiological support synchronized with the heart's natural contractions. It respects the natural blood flow and does not require aortic bypass surgery. It is the first miniaturized device - barely 10 cm in size - that is adjustable to patients' needs, like a pacemaker, to treat patients with varying degrees of severity. It has no external driveline as it is recharged via a wireless transcutaneous energy transfer system (TET). The device is implanted using a minimally invasive beating-heart procedure, commonly performed by cardiac surgeons, which, on average lasts 90 minutes.

Second cause of death in the world after cancer, severe heart failure is a degenerative disease that progresses to a severe form, resulting in an inability of the heart to contract effectively. Each year, 200,000 patients are not managed effectively due to lack of treatment.

## About FineHeart

FineHeart is a clinical stage medical device company based in Bordeaux. Its innovative product, FLOWMAKER®, with the potential to treat 200,000 patients with severe heart failure each year. FineHeart will initially target the 50,000 most severe patients who are eligible for cardiac assistance. Initial estimates value this market segment to be worth over US\$5 billion.

Founded in 2010, by a team of internationally renowned cardiac surgeons and electro-physiologists: Dr. Stéphane Garrigue, PhD, CSO co-inventor of the FLOWMAKER®; Dr. Philippe Ritter, MS, co-inventor of cardiac resynchronization (CRT); and Arnaud Mascarell, FineHeart's CEO. The company holds a portfolio of 78 patents in 20 families.

FineHeart is supported by a wide pool of public, institutional, industrial and independent investors: Lauak Group, Doliam, Med-INNOV, FineHeart Founders' Holding representing domestic and international private investors mainly from the cardiology sector, and the European Investment Fund, Verve Ventures as well as historical shareholders Irdi, Aquiti, Galia, Broadview Ventures, and M Capital. FineHeart also benefits from the financial support of the European Union, Bpifrance, the New Aquitaine Region and the Centre Region.

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## Contacts

### Europe

Media Relations  
Annie-Florence Loyer [afloyer@newcap.fr](mailto:afloyer@newcap.fr)  
+33 (6) 88 20 35

### FineHeart Communications

James Palmer  
[j.palmer@orpheonfinance.com](mailto:j.palmer@orpheonfinance.com)  
+33 (0) 7 60 92 77 72

28 Avenue Gustave Eiffel,  
Bâtiment C, 33600 Pessac - FR  
[contact@fine-heart.com](mailto:contact@fine-heart.com)  
+33 5 64 31 18 40