

Severe Heart Failure Treatment

FineHeart Successfully Raises €15 million Series B funding With Industrial and Independent Investors

The First In Human implantation of the ICOMS FLOWMAKER® is assured following this financing

Bordeaux, France (June 1, 2021) – FineHeart S.A, a preclinical medical device company that has developed the ICOMS FLOWMAKER®, an Implantable Cardiac Output Management System designed to address the unmet need of patients suffering from severe heart failure, today announced the successful completion of a €15 million funding round. This enables FineHeart to prepare for First-In-Human clinical trials planned for 2022.

The financing was realized with a pool of industrial and independent investors:

- Two industrial groups: Lauak, making its first investment since creation outside the aeronautics sector, and Doliam, a specialist in implantable medical components and devices.
- FineHeart Founders' Holding, brings together international private investors, mainly from the cardiology sector, and the European investment fund Verve Ventures. They join historical shareholders Irdi, Aquiti, Galia, Broadview Ventures, and M Capital, who have renewed their support for FineHeart.

*“I am delighted to have completed this financing with such a complimentary pool of investors who are committed to FineHeart’s long-term growth and who share our ambition to become a new name worldwide in medical devices for cardiology,” said **Arnaud Mascarell, CEO and Co-founder FineHeart**. “This consortium of shareholders represents a new approach, going beyond straightforward financial support. We have brought together know-how from the world of technological excellence and renowned medical expertise, shown by the substantial contribution from cardiologists, who have individually invested through the FineHeart Founders Holding Company. I am extremely grateful for their support, and I reiterate our determination to deliver the disruptive treatment that the ICOMS FLOWMAKER® represents.”*

This financing operation is a significant achievement for FineHeart in the run-up to clinical trials. The ICOMS FLOWMAKER® has successfully accomplished all the key milestones prior to First-In-Human trials. The international medical community welcomed these preclinical trial results as an efficient solution to treat severe heart failure, thus validating the potential for the ICOMS FLOWMAKER® as an effective treatment.

***Mikel Charritton, joint CEO of Lauak Group**, stated, “Our investment in FineHeart shows our willingness to diversify our business by playing a key role in the development, manufacturing, and market launch of high added value medical products. Since Luauk was founded, with an aeronautic focus, we have built our development on innovation, providing world-renowned expertise in the manufacturing of high-precision, complex parts.”*

*“Since our first involvement with FineHeart more than two years ago, we have been impressed by their motivation and breakthrough approach, the strength of the team, and the successful delivery of milestones. We are delighted to ramp up our financial support and leverage our know-how in bringing the ICOMS FLOWMAKER® to market as a truly disruptive treatment for severe heart failure,” said **Etienne Flesch, Managing Director of Doliam Group**.*

The ICOMS FLOWMAKER project has triggered significant interest from independent international investors. Cardiologists represent a substantial weighting, together with investors who have seen family members suffer from severe heart failure. Their investments are regrouped in the Founders’ Holding company (FH Founders).

*“The development of a heart treatment solution as innovative as the ICOMS FLOWMAKER® requires support and long-term investment to succeed. I am delighted to be part of this exciting project, alongside committed physicians, aiming to improve the quality of life for patients with severe heart failure,” said **Mrs. Sarah Collier, Benton L.A. (USA)**.*

Jean-Luc Boulnois, Executive Chairman of FineHeart, declared, “On behalf of all longstanding and new investors, I would like to underline the remarkable and ground-breaking clinical progress that the ICOMS FLOWMAKER® represents. It has the potential to be a first-in-class treatment for thousands of severe heart failure patients. With this latest fundraising, we now hold all necessary resources to ramp up the development of our breakthrough technology, and notably the manufacturing capabilities required for First-In-Human clinical trials.”

To date, FineHeart has raised more than €35 million since its inception in 2010. Today the company has a staff of 40, essentially focused on R&D and expertise in quality and regulatory affairs. FineHeart has an international Scientific Medical Board of world-renowned members.

Advisors to this operation:

Financial advisors: Agile Capital Markets

Legal advisors to FineHeart: Reboul Associés, Olivier Mourain, Geoffrey Benitsa

Legal advisors to Investors: Choate, Brian Goldstein



About the ICOMS FLOWMAKER®

The ICOMS 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, and lasts on average 90 minutes.

FineHeart demonstrates that the protocol for implanting and removing the ICOMS FLOWMAKER® resolves the severe complications associated with implantation of left ventricle assist device (LVAD) surgery, which deteriorates the fragile cardiovascular condition of the patients treated. Today, within two years of the implantation of a classic LVAD, 80% of patients develop a severe complication that makes them dependent on their assistance device.

About Heart Failure

Heart failure (HF) is the second leading cause of death in the United States and Europe and has become a global pandemic affecting 26 million people worldwide, with a steadily rising incidence (over one million new cases in G8 countries). This degenerative disease is associated with a reduced quality of life, frequent, costly hospitalizations, and early mortality. Cases of severe HF require a device to improve the pumping capacity of the left ventricle. Despite the pressing need, current LVADs are bulky, which causes significant myocardial damage. They are associated with a risk of infection, bleeding, and thrombosis, which is why they are almost exclusively implanted in very severe patients with short life expectancy. In the event of a sudden attack (cardiogenic shock), it is often necessary to wait before deciding whether to implant an LVAD and force physicians to resort to temporary circulatory assist solutions. These less invasive aids are limited in time (30 days maximum) and require the patient is bedridden a large part of the time. The prospect of a single device, such as the ICOMS FLOWMAKER®, that is capable of providing both temporary support (with no time limit and preserving the patient's mobility) and permanent support if the patient does not recover sufficiently from the shock, constitutes a paradigm shift in the way severe Heart Failure patients will be treated.

About FineHeart - www.fineheart.fr

FineHeart is a French medical device company headquartered in Bordeaux. Its patented ICOMS innovation holds the potential to treat 200,000 severe heart failure patients annually, with FineHeart initially targeting the 50,000 patients who are eligible for hemodynamic support but today are not treated by current LVADs; a \$5B unmet market need.

FineHeart was founded in 2010 by a team of internationally renowned cardiac surgeons and cardiologists, led by Stephane Garrigue, MD, PhD, CSO, Philippe Ritter, MD, MS, co-inventor of cardiac resynchronization therapy (CRT), and FineHeart CEO, Arnaud Mascarell. The company benefits today from 17 patent families.

FineHeart is supported by major U.S. venture capital firms specializing in the cardiovascular space, prime French investors, the European Union, and Region Nouvelle Aquitaine and Region Centre. It has been recognized by FierceMedTech as one of its "Fierce 15," designating it as one of the most promising private MedTech companies in the industry.

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