



FineHeart Completes First Successful Chronic In-Vivo Study of its ICOMS Device Intended for the Treatment of Severe Heart Failure

First destination therapy that restores natural heart pumping capacity; potential game changer for more than 200,000 untreated severe heart failure patients per year

Bordeaux, May 5, 2020 – FineHeart, a French medical device company, today announced the success of a seven-day preclinical study to evaluate its Implantable Cardiac Output Management System (ICOMS), the first fully Intra-Ventricular Flow Accelerator synchronized to the native heartbeat to restore natural heart pumping capacity.

Harvard Medical School Professor Mandeep R. Mehra, MD, The William Harvey Distinguished Chair in Cardiovascular Medicine at Brigham and Women’s Hospital, Boston, and FineHeart scientific advisory board member, states: *“The concept of the ICOMS is a critical advance in our search for an easily implantable, low energy requiring, fully internalized and physiological flow characteristic pump. Such progress has the potential to become a game changer. The results of this preliminary chronic study are extremely promising and set the stage for the next phase of the product’s development.”*

Heart failure (HF) is the second leading cause of death in the U.S. and Europe. It is a degenerative disease leading to poor quality of life, frequent costly hospitalizations and early mortality. Severe HF requires device-based therapy to enhance the left ventricle’s pumping capacity. Despite the need, currently available left ventricular assist devices (LVADs) are large, cause substantial myocardial damage, are subject to infection and thrombosis risk, and are therefore used in a small proportion of the HF population.

FineHeart CEO Arnaud Mascarell, MS, MBA comments on the company’s advancements, stating: *“We have studied and better understood intraventricular fluid mechanics induced by heart contractions then designed the first pump able to sense and support heart hemodynamics. Today, the ICOMS is functional and has reached design-freeze. These strong initial chronic results open the door to longer preclinical trials already in preparation and to a First in Human study within 18 months.”*

University of Michigan Professor of Cardiac Surgery Francis D. Pagani, MD, PhD, Director of the Center for Circulatory Support and FineHeart scientific advisory board member, presented ICOMS data at the American Association for Thoracic Surgery (AATS) Mechanical Support for the Heart and Lung Symposium in Houston on February 15, 2020.

“After multiple acute studies conducted over years of development, this first chronic trial confirms the promising results of the ICOMS in overcoming many of the challenges associated with LVADs currently on the market,” said Dr. Pagani. “The ability to support natural heart function through a fully implantable, permanent device would dramatically improve heart failure patient quality of life and long-term outcomes.”

More specifically, the study confirmed:

- **Simple surgery with implant stability:** ICOMS is implanted via mini-thoracotomy through a trans-apical approach into the beating heart without cardiopulmonary bypass. The design eliminates the typical LVAD outflow cannula to the ascending aorta.

- **Sustained blood cell integrity:** With a pump outlet positioned entirely inside the ventricle, ICOMS has shown less shear stress applied to red blood cells and preserved pulsatility, which therefore should result in lower rates of gastrointestinal bleeding. The outstanding low level of hemolysis measured during the trial confirmed performant and reliable hemocompatibility.
- **Efficient synchronization and device tolerance:** The ICOMS hemodynamically supported and preserved native heart cycles, maintaining regular heartbeat and healthy blood flow throughout the seven days of follow-up.

About ICOMS

FineHeart's Implantable Cardiac Output Management System (ICOMS) is a smart, unique, wirelessly powered, flow accelerator device that is able to restore normal cardiac output while preserving the heart's innate contractility. It is the first permanent pump that is fully implanted inside the left ventricle, synchronized to native heartbeat and adjustable in its level of cardiac output support, thereby eliminating a driveline by virtue of an implantable battery charged transcutaneously (TET) system.

About FineHeart – www.fine-heart.com

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 16 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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