FineHeart
A Healthier Life With Every Beat

Press Release

FineHeart Achieves Milestone For its Miniaturized Heart Pump Technology with Successful Completion of 30-Day Preclinical Study

The ICOMS device is the first destination therapy that restores natural heart pumping capacity

This successful milestone is a major step towards first in human clinical trials

Bordeaux, France - October 20, 2020. – FineHeart, SA, a preclinical-stage medical device company developing an Implantable Cardiac Output Management System (ICOMS) to address the unmet need of patients suffering from severe heart failure, today announced the successful completion of a 30-day preclinical study. The 30-day trial confirms the device's ability to provide hemodynamic performance with pulsed and continuous increased cardiac output of up to 6L/min; it demonstrated a low risk of hemolysis and thrombosis.

The device was safely tested as being well-tolerated with no related adverse event observed during the 30 days.

"*The success of this 30-day in vivo study is a significant milestone for FineHeart as we work towards first-in-human clinical trials and prove ICOMS technology as a potential game-changer in saving patients from heart failure," said Arnaud Mascarell, CEO and Founder, FineHeart. "Hospital readmission rates following LVAD surgery is staggering, with patients being re-admitted two to five times in the first six months following LVAD surgery. Our team has developed a technology to mitigate complications and issues, such as rehospitalization. With multiple acute studies and rigorous years of development, under our belt, the outcomes reinforce the impact ICOMS will have on the current standard of care.*"

An innovative hybrid between a pacemaker and a cardiac assist device, FineHeart's ICOMS technology is the first fully intraventricular flow accelerator providing pulsatile, physiologic support of the native heart function without by-pass to the aorta. It respects the natural blood flow and is synchronized with the heart's contractions. No more than four inches long, ICOMS is the first miniaturized device with adjustable flow, allowing a physician to modify blood flow based on the patient's heart failure severity.

The device is implanted in a mini-invasive procedure familiar to cardiac surgeons and takes under ninety minutes to be put in place.

With high performance and low energy consumption, the distinctive design allows the device to run on rechargeable wireless power (no electrical lines through the skin), substantially reducing complications and rehospitalizations. The design of the product is finalized, and manufacturing partners have been confirmed.

"*ICOMS continues to show promise as an easily implantable device with the potential for lowering the complications experienced with current generation LVADs. After the encouraging results from the first seven-day preclinical study, the success of this 30-day trial moves FineHeart's ICOMS closer to human trials which will help to establish this as a groundbreaking way forward to treat heart failure patients,*" states 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.

"***The results of this study are impressive.*** *It validates the ICOMS ability to generate efficient blood flow with a lowered risk of damage to platelets and red blood cells, reducing the likelihood of bleeding and thrombosis,*" said University of Michigan Professor of Cardiac Surgery Francis D. Pagani, MD, Ph.D., Director of the Center for Circulatory Support and FineHeart scientific advisory board member. "*The technology's unique ability to support the natural heart function for long-term benefits addresses a significant unmet clinical need and could improve the quality of life for hundreds of thousands of patients suffering from severe heart failure.*"

Heart failure (HF) is the second leading cause of death in the US and Europe, a global pandemic affecting at least 26 million people worldwide and increasing prevalence. 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, LVADs are large, cause substantial myocardial damage, are subject to infection and thrombosis risk, and the FDA restricts usage to cover only a small proportion of the HF population.

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, Ph.D., 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, BpiFrance 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.

ICOMS is not approved for use or sale in any geography. Please visit www.fineheart.fr for additional information.

Contacts

US et International
Dana Summers
Penman PR pour FineHeart
dana@penmanpr.com

Europe
NewCap Media Relations
Annie-Florence Loyer
afloyer@newcap.fr
+33 (6) 88 20 35 59

Agile Capital Markets
Sophie Baratte
Sophie.baratte@agilecapitalmarkets.com