FineHeart
A Healthier Life With Every Beat

Press Release

FineHeart Successfully Tests the Implantable, Wireless Transcutaneous Energy Transfer (TET) System for powering its ICOMS Heart Pump

A major step and a critical milestone achieved prior to First In Human clinical trials

- FineHeart's TET is a system with no percutaneous driveline that transfers energy through the skin to charge the ICOMS pump battery
- TET is rapidly implantable (less than 15 mins) and will give patients autonomy
- The elimination of the external driveline will reduce infections and complications causing high rates of mortality

Bordeaux, France – January 12, 2021 – 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 seven-day study of its Transcutaneous Energy Transfer (TET) System for recharging the ICOMS implantable battery.

"We are delighted to have succeeded in this major technological advancement proving the ability to power a Cardiac Assist device via an intelligent and minimally invasive TET system. This is a breakthrough in treating patients with severe heart failure who will be able regain a quasi-normal quality of life, without any device connected to their skin." said **Arnaud Mascarell, CEO and Founder, FineHeart.** " We are very pleased with the success of this study, which is a world first: to date, no TET system of this size supporting the pulsatility function has been realised. This study marks another crucial milestone for FineHeart and further validates the design freeze of our technology."

The trial confirms the TET's ability to operate and provide power to the miniature heart pump in pulsatile mode and makes it the smallest TET system study ever completed in this domain. The energy transfer system was safely tested as quickly implantable (15 minutes), having low energy consumption and avoiding tissue heat absorption. These benefits will ease recovery for already fragile patients. Furthermore, eliminating an external driveline removes the main cause of infection and complications for patients implanted with an LVAD and will therefore reduce rates of morbidity and mortality.

The ICOMS intracardiac location and its ability to synchronize with the heart's natural contractions make it exceptionally energy efficient. ICOMS is designed to support, rather than replace and especially not to go against the direction of the natural blood flow and fight against very high pressure gradients, as the devices currently on the market do. ICOMS 'feeds off' the intracardiac force generated with each contraction and relies on their strength to generate additional and therapeutic blood flow. While respecting native cardiac flows, this support allows a significant reduction in its consumption, up to 5 times smaller than that observed in the Cardiac Assistance Devices (DAVG) currently on the market.

About the In-vivo study

The TET system was implanted for seven days, with five temperature sensors located throughout the internal coil pocket. The inner coil diameter is 8cm at 0.8 cm thick (same dimensions as an internal defibrillator, a device implanted daily in the G8 countries).

Heating was monitored for seven days with a consumption profile corresponding to a system operating at full speed, under extreme consumption conditions, well above nominal modes. The study showed that the average heating increase was around 1.5 +/- 0.2 °C, resulting in no tissue damage and no infection.

“The results of this study are remarkable and demonstrate that this small, mini-invasive TET system is functional and compatible with FDA guidelines and current regulations,” said Professor Michael Acker, M.D., Head of the Cardiac Surgery at the University of Pennsylvania Medical Center and FineHeart scientific advisory board member. “The ICOMS technology’s unique ability to replicate the volumetric displacement of the blood, beat by beat, by generating physiological cardiac flows addresses a significant unmet clinical need and could improve the quality of life for a huge population suffering from severe heart failure today and tomorrow.”

About 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 ICOMS

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 less than ninety minutes to be put in place.

About FineHeart

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 18 patent families and 69 patents.

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.

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

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