FineHeart
A healthier life with every beat

Press Release

Severe Heart Failure Treatment

FineHeart completes 1st successful step in ISO 13485:2016 certification

Bordeaux, France November 29, 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 it has completed the 1st step in its ISO 13485:2016 certification following a successful BSI audit.

"This milestone is a recognition of the excellence of our quality management and FineHeart's commitment to developing an innovative healthcare device to meet the needs of patients with severe heart failure. Our processes are audited by BSI, one of the world's leading Certification companies, and has been ratified as meeting the requirements of the international standard ISO 13485:2016," explains Virginie Rivet, FineHeart's Director of Quality and Regulatory Affairs.

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 treated patients. Within two years of the implantation of a classic LVAD, 80% of patients develop a severe complications that make them dependent on their assistance device.

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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