Press Release

Treatment of Severe Heart Failure - AI

FineHeart certified ISO 13485 : 2016 for Medical Device Quality Management Systems

ICOMS FLOWMAKER®, First Fully Implantable Electro-Physiological Cardiac Assistance Device

Bordeaux, France, **September 5, 2022** - FineHeart S.A, a preclinical medical device company that has developed the ICOMS FLOWMAKER®, a fully Implantable Cardiac Output Management System designed to address the unmet need of patients suffering from severe heart failure, today announced its ISO 13485 : 2016 certification. This certifies the compliance of FineHeart's quality management system with medical device industry regulations and has been issued following an audit by BSI, the independent, internationally recognized, accreditation organization.

“The whole team is extremely proud to have accomplished this crucial step in the development of the ICOMS FLOWMAKER®. The ISO 13485 certification confirms the quality standards that have always prevailed within the company, from the design to the fully in-house production of our breakthrough cardiac assistance device. Our goal is to allow patients suffering from severe heart failure to return to a normal life, thanks to our device for which First In Human trials are scheduled to begin next year." declared **Arnaud Mascarell, CEO & co-founder of FineHeart**.

“We are delighted to have obtained ISO 13485:2016 certification. This demonstrates FineHeart's ability to produce quality complex medical devices and related services that systematically meet the demands of patient safety and relevant regulatory requirements” explained Virginie **Rivet, FineHeart’s Quality and Regulatory Affairs Director**

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, which, on average lasts 90 minutes.

About FineHeart

FineHeart is a medical device company that is developing its innovative ground-breaking product, ICOMS FLOWMAKER®, with the potential to treat 200,000 patients with severe heart failure each year. First-In-Human trials are expected in 2023. FineHeart will initially target the 50,000 most severe patients who are eligible for cardiac assistance. Initial estimates value this market segment to be worth over US$5 billion.

Founded in 2010, FineHeart is based in Bordeaux employing close to 50 employees. It is led by a team of internationally renowned cardiac surgeons and electro-physiologists: Dr. Stéphane Garrigue, PhD, CSO co-inventor of ICOMS FLOWMAKER®; Dr. Philippe Ritter, MS, co-inventor of cardiac resynchronization (CRT); and Arnaud Mascarell, FineHeart's CEO. The company holds a portfolio of 72 patents in 18 families.

FineHeart is supported by a wide pool of public and private industrial and independent investors: Lauak Group, Doliam, Med-INNOV, FineHeart Founders' Holding representing domestic and international private investors, mainly from the cardiology sector, and the European investment fund Verve Ventures as well as historical shareholders Irdi, Aquiti, Galia, Broadview Ventures, and M Capital. FineHeart also benefits from the financial support of the European Union, Bpifrance, the New Aquitaine Region and the Centre Region.

Contacts

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

FineHeart Communications
James Palmer
j.palmer@orpheonfinance.com
+33 (0) 7 60 92 77 72

28 Avenue Gustave Eiffel,
Bâtiment C, 33600 Pessac - FR Tel:
+33 5 64 31 18 40
contact@fine-heart.com