

Sunshine Heart Implants First Patient in C-Pulse COUNTER HF U.S. Pivotal Trial

Globe Newswire

Sunshine Heart, Inc. (Nasdaq:SSH) announced today the first patient implant in the Company's U.S. pivotal trial, COUNTER HF. The COUNTER HF study is a prospective, randomized, multi-center, controlled trial that will evaluate the safety and efficacy of the C-Pulse system for the treatment of NYHA Class III and ambulatory Class IV heart failure.

Integral to the COUNTER HF study is the assessment of C-Pulse's unique balloon counterpulsation treatment designed to improve heart function and reduce re-hospitalizations due to worsening heart failure.

"We are excited to be part of this innovative clinical trial," said cardiothoracic surgeon, Sanjeev Aggarwal, M.D., Director of Mechanical Circulatory Support and principal study investigator at Saint Luke's Mid America Heart Institute of Kansas City. "Based on the positive clinical results from our experience during the feasibility study, we are very much looking forward to participating in the COUNTER HF pivotal study. The C-Pulse system, in comparison to other devices used for circulatory support, offers the advantage of implantation through a truly minimally invasive approach without the need for cardiopulmonary bypass or sternal division. Its non-blood contacting interface obviates the need for anticoagulation and allows patients to untether from the device for short periods of time. We are excited to have the opportunity to further investigate the potential benefits of this technology in heart failure patients through this important pivotal study."

"The COUNTER HF study is important for the many heart failure patients who are not being successfully treated with existing therapies," said David Rosa, CEO of Sunshine Heart. "We are pleased to have St. Luke's Mid-America Heart Institute enroll and implant our first patient in the COUNTER HF pivotal trial. They were the top enrolling clinical site in our recently completed U.S. FDA C-Pulse system feasibility study and we look forward to their continued leadership in this trial."

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