VisCardia Receives US FDA IDE Approval to Start the RECOVER HF Clinical Study

PORTLAND, OREGON, UNITED STATES, July 30, 2024 /EINPresswire.com/ -- VisCardia, Inc. announced today the U.S. Food and Drug Administration (FDA) approval of an Investigational Device Exemption (IDE) to study the safety and effectiveness of the VisONE SDS system, designed to improve patient's quality of life, exercise tolerance, and cardiac performance. This is a key unmet need in the management of moderate to severe Heart Failure patients, who remain symptomatic despite being on Guideline Directed Medical Treatment. In the US alone, the estimated number of Heart Failure patients is around 7 million, and the related healthcare costs are staggering.

This approval allows VisCardia to conduct the pivotal RECOVER-HF study, a randomized, double-blind trial comparing therapy activated (treatment group) and inactivated for the first 6 months (control group) in patients who have systolic heart failure without evidence for ventricular dyssynchrony. The collected safety and effectiveness data will be used in support of a future pre-market application (PMA) in the USA.

Dr. Lee R. Goldberg, University of Pennsylvania, Advanced Heart Failure and Cardiac Transplant, who will serve as the overall principal investigator for the RECOVER-HF study, said, "VisONE SDS therapy could be the disruptive technology needed to close the significant gap in Heart Failure management, and I am excited to lead the pivotal trial in the U.S".

VisCardia previously received FDA Breakthrough Device Designation for the novel Synchronized Diaphragmatic Stimulation (SDS) that recruits the diaphragm as an auxiliary pump to improve blood circulation. The implantable therapy system monitors the cardiac cycle from two electrodes on the underside of the diaphragm and synchronizes a small electrical charge to the diaphragm that causes a localized twitch. The twitch is not felt by the patient and does not impact the breathing cycle, it does change the pressures inside the chest and abdomen in such a way to enhance the pumping function of the heart.

Peter Bauer, CEO of VisCardia, stated, "Bringing this exciting technology to the U.S. has been a

productive collaboration between VisCardia and the FDA. We are very encouraged by the enthusiasm from all investigators and clinical teams who have witnessed the results of this novel therapy”.

About VisONE® SDS® Therapy
VisCardia's Synchronized Diaphragmatic Stimulation (SDS®) system is designed to improve the heart’s performance by recruiting the diaphragm as circulatory support without increasing cardiac demand or having a negative impact on respiration.

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