CVRx®

Press Release

CVRx® Announces First Clinical Procedure with a New Ultrasound-Guided Implant Approach, the Latest Advancement in Barostim™ for the Treatment of Heart Failure Symptoms

MINNEAPOLIS, June 10, 2021 – CVRx®, developer of the world's first FDA-approved neuromodulation device to treat the symptoms of heart failure (HF), announced the completion of the first clinical procedure with the company's new lead implantation approach. The novel ultrasound-guided technique is the latest advancement of CVRx's Barostim™ Baroreflex Activation Therapy (BAT™) to treat the symptoms of HF patients. The new approach further simplifies the implant procedure by using minimally invasive techniques and ultrasound imaging to guide the placement of a small stimulation lead near the targeted carotid baroreceptors.

The procedure was performed by cardiac electrophysiologist James D. Allred, M.D. and vascular surgeon Wells Brabham, M.D., at The Moses H. Cone Memorial Hospital in Greensboro, North Carolina. Commenting on the technology, Dr. Allred said, "This new approach to treatment represents a potentially game-changing advancement in the way we manage patients with HF symptoms. We are excited to participate in this study evaluating the ultrasound-guided approach as a new implant technique to deliver this therapy."

"We are pleased to have participated in this first-in-human procedure at our center," said Dr. Brabham. "We are excited by this new approach and we are happy to contribute towards the investigation of a new way to deliver this important therapy to patients."

"Congratulations to Drs. Allred and Brabham and Moses Cone Hospital on successfully completing this first clinical procedure in the study of this new implant technique," said Nadim Yared, President and CEO of CVRx. "We value our collaboration with them and commend their ongoing efforts to advance neuromodulation to treat HF symptoms."

Barostim is now commercially available to reduce the symptoms of HF for patients who are not indicated for CRT and have a left ventricular ejection fraction of 35% or less. Barostim is also the recipient of the Centers for Medicare and Medicaid Services (CMS) outpatient Transitional Pass-Through Payment Status (TPT) and inpatient New Technology Add-On Payment (NTAP).

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About Heart Failure[1]

Heart failure is a chronic, progressive condition in which the heart muscle is unable to pump enough blood to meet the body's needs for blood and oxygen. In the US, heart failure is estimated to affect 6.9 million adults and is expected to increase by 24% to nearly 8.5 million in 2030. Overall, heart failure is associated with a four-fold increased risk of death and a six to nine times increased risk of sudden cardiac death. Despite current standard of care, the clinical burden remains high. In the US, the total direct and indirect costs of care for HF is estimated at $43.6 billion, with over 70% of costs attributed to medical costs. Without improvements in outcomes, the annual total cost of care in the USA is projected to increase to $69.7 billion by 2030.

About CVRx Barostim™ - Baroreflex Activation Therapy

CVRx's Barostim is the first medical technology approved by the FDA that uses neuromodulation - the power of the brain and nervous system - to improve the symptoms of patients with systolic heart failure. Barostim is delivered by the Barostim NEO™ Generator, an implantable device that uses CVRx-patented technology to send electrical pulses to baroreceptors located in the wall of the carotid artery via a small stimulation lead. Baroreceptors trigger the body's baroreflex which in turn triggers an autonomic response to the heart. The therapy is designed to restore balance to the autonomic nervous system and thereby reduce the symptoms of HF. Barostim received the FDA Breakthrough Device designation and is FDA-approved for use in HF patients in the US. It has also received the CE Mark for HF and resistant hypertension in the European Economic Area. To learn more about Barostim, watch this video.

About CVRx, Inc.

Headquartered in Minneapolis, MN., CVRx® is a leader in innovative medical technologies that address the unmet needs in cardiovascular diseases with safe and effective therapies that harness and harmonize the body's natural systems. CVRx is dedicated to improving patient outcomes, quality of life, and overall cardiovascular health via novel baroreceptor neuromodulation therapies.

CAUTION: Investigational device. Limited by Federal (or United States) law to investigational use.

For a list of all potential benefits and risks go to www.cvrx.com/benefit-risk-analysis/.

Media Contact:
Lisa Murray
Trevi Communications, Inc.
978.750.0333 / 617.835.0396

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[1] https://link.springer.com/article/10.1007/s40273-020-00952-0

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lisa@trevicomm.com