CVRx® Announces that the First Two Patients were Treated in the Phase III Pivotal Trial Evaluating BAROSTIM THERAPY® for the Treatment of Heart Failure

Minneapolis - June 6, 2016 - CVRx, a global medical device company, today announced that the first two patients have been treated with the BAROSTIM NEO® System in the Baroreflex Activation Therapy for Heart Failure Pivotal Clinical Trial (BeAT-HF). The procedures were done at the University of California San Francisco and Abrazo Arizona Heart Hospital in Phoenix, Arizona. More than 20 patients have been enrolled and are being evaluated for eligibility.

BeAT-HF is a Phase III randomized, controlled clinical trial that studies the safety and efficacy of BAROSTIM THERAPY, the only therapy that is designed to simultaneously reduce sympathetic nervous system activity while restoring parasympathetic activity, for the treatment of heart failure. The trial will randomize 480 patients who suffer from heart failure with a reduced ejection fraction and who have no additional treatment alternatives available. BeAT-HF has achieved Expedited Access Pathway (EAP) designation by FDA for its focus on this unmet clinical need.

“We are very excited by the enrollment and treatment of the first patients in the BeAT-HF Pivotal Clinical Trial. The patients we are including suffer from a very poor quality of life and an increased risk of heart failure-related hospitalizations, and they have no further treatment options,” said Michael Zile, M.D., Professor of Medicine at the Medical University of South Carolina and Chair of the BeAT-HF Executive Steering Committee. “BAROSTIM THERAPY has already demonstrated unprecedented symptom improvement through HOPE4HF, a Phase II randomized, controlled clinical trial, and we are looking forward to similar patient outcomes during BeAT-HF.”

About the BeAT-HF Pivotal Clinical Trial

The BeAT-HF Phase III clinical trial is designed to demonstrate the safety of BAROSTIM NEO and its effectiveness on symptoms and clinical outcomes in patients suffering from chronic heart failure. The trial is intended to provide the basis for market approval in the US.

Key Eligibility Criteria:

- NYHA Class III
- Left Ventricular Ejection Fraction ≤ 35%
- Elevated NTproBNP
- On current heart failure guideline-directed medical therapy

About BAROSTIM THERAPY for Heart Failure

Positive safety and efficacy results from HOPE4HF, a 146-patient randomized, controlled clinical trial were presented at the American College of Cardiology, Heart Rhythm Society and the European Society of Cardiology Heart Failure conference in 2015. Results at six months showed that patient symptoms, functional capacity, and cardiovascular function were significantly improved, while heart failure hospitalization days were reduced in BAROSTIM THERAPY patients compared to control patients. The favorable data are now published in JACC-HF and European Journal of Heart Failure.[1, 2]

About BAROSTIM NEO ®

BAROSTIM NEO uses CVRx-patented technology designed to trigger the body's main cardiovascular reflex to treat patients suffering from chronic heart failure. BAROSTIM NEO is also a treatment option for patients with resistant hypertension. The BAROSTIM NEO System is designed to electrically activate the baroreflex, the body's natural mechanism to regulate cardiovascular function. By activating this afferent pathway, BAROSTIM THERAPY reduces sympathetic activity and increases parasympathetic activity, ultimately restoring autonomic balance.

Key unique benefits:

- BAROSTIM NEO ensures 100 percent adherence to treatment
- It continuously stimulates the baroreflex, and can be adjusted to meet each patient's individual therapeutic needs
- It is compatible with, and complementary to, implantable cardiac rhythm management devices[3]
- BAROSTIM NEO can be turned on and off to demonstrate acute results
- It is a reversible treatment, as therapy can be turned off

About Heart Failure

Heart failure is a serious condition that impairs heart function, resulting in shortness of breath, exercise intolerance and fluid retention. In the United States, heart failure is estimated to affect 5.1 million adults.[4] 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. The direct and indirect costs of heart failure are estimated to be $32 billion in the United States in 2013.[4]

About CVRx, Inc.

CVRx, Inc. is a privately held company founded in 2001 and headquartered in Minneapolis, Minnesota. The company has developed the second-generation BAROSTIM NEO, a minimally-invasive implantable system and the only device CE Marked for the separate indications of heart failure and resistant hypertension. BAROSTIM NEO is commercially available in over 20 countries and under clinical evaluation for the treatment of heart failure and hypertension in the United States. The company's BAROSTIM NEO LEGACY™ holds Humanitarian Device Exemption (HDE) approval from FDA, deeming it safe for use in hypertensive patients who were responders to the first-generation BAROSTIM THERAPY with Rheos Carotid Sinus Lead System.

For more information, visit CVRx or Clinical Trials.gov.

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Footnotes:

1. Abraham W, et al. Baroreflex Activation Therapy for the Treatment of Heart Failure with a Reduced Ejection Fraction, JACC: Heart Failure 2015; 3(6):487-496

2. Zile M, et al. Baroreflex Activation Therapy for the Treatment of Heart Failure with a Reduced Ejection Fraction: Safety and Efficacy in Patients with and without Cardiac Resynchronization Therapy, European Journal of Heart Failure (2015), doi: 10.1002/ejhf.299

3. Madershahian N, et al. Baroreflex activation therapy in patients with preexisting implantable cardioverter-defibrillator: Compatible, complementary therapies. Europace Feb, 2014

4. Go A, Heart Disease and Stroke Statistics. American Heart Association – 2013 Update. Circulation 2013;127:e6-e245

CAUTION: BAROSTIM NEO® is an investigational device and is limited by United States law to investigational use. Exclusively for Clinical Investigations for the treatment of heart failure and resistant hypertension in Canada.