CVRx® Receives CE Mark Approval of the Barostim *neo* System™ for the Treatment of Heart Failure

Minneapolis – September 29, 2014 – CVRx, Inc., a private medical device company, announced today it received CE Mark approval from the National Standards Authority of Ireland (NSAI) of the Barostim *neo* System™ for the treatment of heart failure. The therapy is approved for use in heart failure patients having an ejection fraction ≤ 35% and a New York Heart Failure Classification of III without restriction on QRS duration, concomitant medical device treatment or presence of atrial fibrillation. The system was approved for commercialization in Europe based on patient results from randomized, controlled clinical studies conducted in Europe, Canada and the United States.

"This is a tremendous milestone for CVRx. Barostim *neo* is the only implantable device which has received CE Mark approval for patients with heart failure in addition to CE Mark approval for patients with resistant hypertension. We are very encouraged with the safety, performance, and health care utilization data related to Barostim *neo* for both indications. We appreciate the clinical rigor NSAI used for this CE Mark approval. This places CVRx in a very unique position" said Nadim Yared, CEO of CVRx.

"We are impressed by the results we are seeing to date with Barostim Therapy. In our single center study we documented a significant reduction in sympathetic activity which directly correlated into reduced hospitalizations.[1] This is the type of standard we are looking for when treating patients with heart failure. We are elated that the therapy is now commercially available" said Professor Edoardo Gronda from IRCC MultiMedica in Milan, Italy.

About Barostim Therapy™

CVRx completed enrollment of a 140 patient randomized, controlled clinical trial to determine the performance of Barostim Therapy for patients suffering from chronic heart failure with advanced symptoms. Promising results from an earlier study demonstrating clinical improvement and reduced hospitalizations have been presented and published.[1] The six month results from the randomized, controlled trial are being prepared for publication.

Five-year results of the 322-patient sham-controlled Rheos Hypertension Trial were presented at the American Society of Hypertension and the joint European and International Societies of Hypertension annual scientific conferences in May and June of 2014. The results showed a statistically significant reduction of systolic and diastolic blood pressure in excess of 32mmHg and 17mmHg, respectively, over the course of 5

(more)

years. In addition, the long term safety profile of the therapy proved to be excellent with very low rates of stroke, myocardial infarction and worsening of carotid stenosis in this population of patients with advanced hypertension.[2,3]

Barostim Therapy is included in the joint European Society of Hypertension and European Society of Cardiology guidelines for the treatment of resistant hypertension that were published in June, 2013.[6]

About Barostim *neo*™

Barostim *neo* is a second generation device that uses CVRx-patented technology that is designed to trigger the body's own natural blood flow regulation system to treat patients suffering from chronic heart failure and resistant hypertension. The system works by electrically activating the baroreceptors, the body's natural sensors that regulate cardiovascular function. By activating this afferent pathway, Barostim restores sympatho-vagal balance by reducing sympathetic activity and increasing parasympathetic activity.

Key unique benefits:

- The Barostim *neo* can be turned on and off to demonstrate acute results;
- It can be adjusted to meet each patient's individual therapy needs;
- It is a reversible treatment;
- It provides 100 percent compliance to treatment by continuously activating the baroreflex; and
- It is compatible with and complementary to implantable cardio-defibrillators and cardiac resynchronization therapy[5]

About Heart Failure

In heart failure, heart function is impaired, resulting in shortness of breath, exercise intolerance and fluid retention. In the United States, heart failure is estimated to affect 5.1 million adults.[7] 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.[7]

About Hypertension

In Europe, the prevalence of hypertension is estimated to be between 30-45% of the general population.[6] In the United States, hypertension affects 77.9 million people.[7] Worldwide, hypertension is estimated to cause one in every eight deaths.[7] It is a major risk factor for cardiovascular disease, morbidity and mortality. Twenty-five percent of

people with hypertension cannot adequately control their hypertension with medications and lifestyle modifications.[8,9] It is a disease that needs new treatment solutions.

About CVRx, Inc.

CVRx, Inc. is a privately held company founded in 2001 and headquartered in Minneapolis. The company has developed the second generation Barostim *neo*, an implantable system designed to treat heart failure and hypertension (high blood pressure). Barostim *neo* has received CE Marking for the treatment of heart failure in addition to CE Marking for hypertension in Europe. It is under clinical evaluation for the treatment of heart failure and hypertension in the United States.

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Footnotes:

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5. Madershahian N, et al. Baroreflex activation therapy in patients with preexisting implantable cardioverter-defibrilator: Compatible, complementary therapies. *Europace* Feb, 2014
6. Mancia G, et al. 2013 ESH/ESC Guidelines for the management of arterial hypertension. *European Heart Journal* 2013 34 (28): 2159-2219
7. Go A, Heart Disease and Stroke Statistics. American Heart Association – 2013 Update. *Circulation* 2013;127:e6-e245
8. Prospective Studies Collaboration. *Lancet* 2002;360:1903-1913
9. Chobanian AV. JNC 7: Complete Report. *JAMA* 2003;289:2560-2572

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.