CVRx® Achieves Two Significant Milestones for its Heart Failure and Hypertension Businesses

Minneapolis – June 9, 2014 – CVRx, Inc., a private medical device company, announced today it achieved two significant milestones in its heart failure and hypertension businesses. "We are very excited to announce that CVRx has completed enrollment of our Barostim HOPE4HF heart failure study and that the French Ministry of Health has selected Barostim Therapy™ for Resistant Hypertension as one of five investigator-initiated studies it will fund beginning in 2014. We feel that these are strong indications that physicians and health care systems recognize that there are unmet medical needs with respect to these two large disease states and that Barostim Therapy is a viable treatment option," said Nadim Yared, Chief Executive Officer at CVRx.

CVRx Completes Barostim HOPE4HF Study Enrollments

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. Patients were randomized to receive optimal medical management or Barostim Therapy plus optimal medical management. Patients were enrolled in the United States, Germany, Italy, and Canada. Results will be used to obtain regulatory approval in Europe in addition to seeking approval to conduct a larger clinical trial in the United States to enter the U.S. market. Results from a single center heart failure study at IRCC MultiMedica in Milan, Italy were recently presented at American Cardiology Conference (ACC) Scientific Sessions 2014 by Professor Edoardo Gronda and colleagues.[1] The presented data showed a significant reduction in health care utilization for his eleven patients when comparing the cumulative hospitalization of the group 12 months prior to receiving Barostim Therapy as compared to 12 months after beginning therapy. "We are extremely encouraged by the results we are seeing to date with Barostim Therapy. In our study we documented a significant reduction in sympathetic activity which directly correlated into improved health outcomes.[2] This is the type of standard we are looking for when treating patients with heart failure," said Professor Gronda.

The French Ministry of Health will Fund an Investigator-Initiated Study to Evaluate the Incremental Cost Effectiveness (ICER) of Barostim for Patients with Resistant Hypertension

The investigator-initiated medicoEconomic evaluation of baroreceptor STIMulation for the treatment of Resistant HyperTensioN (ESTIM-rHTN) study was one of 5 studies selected

(more)

in 2014 by the French Ministry of Health for public funding and sponsored by the Nancy University Hospital (Nancy, France). Professor Patrick Rossignol, Nancy, France, and Professor Michel Azizi, Georges Pompidou European Hospital, Paris, France, are the principal investigators. The study will randomize 128 patients to receive optimal medical management or Barostim Therapy plus optimal medical management at 13 centers designated as Hypertension Centers of Excellence across France.

About Barostim *neo*™

Barostim *neo* is CE Marked for the treatment of resistant hypertension and is commercially available in Europe. The 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.[3]

Barostim *neo* is a second generation device that uses CVRx-patented technology designed to trigger the body's own natural blood flow regulation system to treat heart failure and hypertension. The system works by electrically activating the baroreceptors, the body's natural blood pressure sensors that regulate cardiovascular function. These baroreceptors are located on the carotid artery. When activated by Barostim *neo*, signals are sent through neural pathways to the brain, which responds by telling the:

- Arteries to relax, making it easier for blood to flow through the body and reducing cardiac exertion;
- Heart to slow down, allowing more time for the organ to fill with blood; and
- Kidneys to reduce fluid in the body, lowering both excessive blood pressure and workload on the heart.

This unique, patented technology has the potential to improve quality of life and reduce health risks associated with heart failure, including heart and kidney disease, stroke and death. Other key potential benefits of Barostim *neo* include that it:

- Can be adjusted to meet each patient's individual therapy needs;
- Is a reversible treatment; and
- Provides 100 percent compliance to treatment, by automatically and continuously activating the baroreflex.

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.[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 Hypertension

In Europe, the prevalence of hypertension is estimated to be between 30-45% of the general population[3] In the United States, hypertension affects 77.9 million people.[5] Worldwide, hypertension is estimated to cause one in every eight deaths.[5] 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.[6,7] 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 hypertension (high blood pressure) and heart failure. Barostim *neo* received CE marking for the treatment of hypertension in Europe. It is under clinical evaluation for the treatment of heart failure in Europe, Canada, and the United States. It is under clinical evaluation for the treatment of hypertension in the United States. For more information on this trial go to www.BloodPressureTrial.com.

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Footnotes:

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3. Mancia G, et al. 2013 ESH/ESC Guidelines for the management of arterial hypertension. *European Heart Journal* 2013 34 (28): 2159-2219
4. Heart Disease and Stroke Statistics. American Heart Association – 2013 Update
5. Go A, Heart Disease and Stroke Statistics. American Heart Association – 2013 Update. *Circulation* 2013;127:e6-e245
6. Prospective Studies Collaboration. *Lancet* 2002;360:1903-1913
7. 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 (in the European Union and Canada [and resistant hypertension in Canada]).