CVRx® Announces First Successful Barostim Heart Failure Commercial Implants in Europe

Minneapolis – October 7, 2014 – CVRx, Inc., a private medical device company, announced today the first 10 heart failure patients treated with the Barostim *neo* System™ under CE Mark approval. The newly approved therapy was made available to a few select Barostim Heart Failure Centers of Excellence beginning October 1st. Asklepios Hospital Altona in Hamburg, The Heart Center of the University of Cologne, Universitätsklinikum Gießen, and Herzzentrum Dresden Universitätsklinik became the first institutions to treat patients with the therapy. Barostim *neo* is approved for use in heart failure patients having an ejection fraction ≤ 35% and in New York Heart Association Functional Class III without restriction on QRS duration, concomitant medical device treatment or presence of atrial fibrillation. The system received CE Mark approval based on patient results from randomized, controlled clinical studies conducted in Europe, Canada and the United States.

"We are very excited to perform the first successful commercially available Barostim heart failure implants in the world. Having performed the first clinical Barostim heart failure implants in 2011 while at the University of Cologne and continuing since, we are very encouraged about the performance of the therapy for our patients. We believe there is a heart failure population who can significantly benefit from Barostim Therapy" said Prof. Dr. Jochen Müller-Ehmsen from Asklepios Hospital Altona.

The Heart Center of the University of Cologne is one of the first European centers to implant the Barostim *neo* System in heart failure patients. "By impacting both limbs of the autonomic nervous system, unique among proposed neuromodulation therapies, Barostim provides integrated autonomic modulation" explained Dr. Marcel Halbach from the Heart Center of the University of Cologne. "Based on strong collaboration with our heart surgery department we feel very confident in offering Barostim Therapy for our heart failure patients" said Prof. Dr. Stephan Baldus.

"We are very excited to be one of the first centers to have a successful Barostim *neo* implant in a patient with heart failure. Barostim Therapy is a potential treatment option for narrow QRS patients as well as patients who have been previously treated with Cardiac Resynchronization Therapy but who are still NYHA Class III with ejection fraction < 35%" said Prof. Dr. Christian Hamm from Universitätsklinikum Gießen.

(more)

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.

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. The therapy is also a treatment option for patients with 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[3]

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 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.

Barostim neo has also received CE marking for the treatment of hypertension. It is under clinical evaluation for the treatment of heart failure and hypertension in the United States.

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Footnotes:

1. Gronda E, et al. Chronic baroreflex activation effects on sympathetic nerve traffic, baroreflex function and cardiac haemodynamics in heart failure: a proof of concept study. *European Journal of Heart Failure* 2014; 16(9):977-983
2. Hoppe U et al. Minimally invasive system for baroreflex activation therapy chronically lowers blood pressure with pacemaker-like safety profile: results from the Barostim *neo* trial. *J Am Soc Hypertens.* 2012;6(4):270-276
3. Madershahian N, et al. Baroreflex activation therapy in patients with preexisting implantable cardioverter-defibrilator: 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.