

News Release

Two-Year Clinical Trial Findings Show Significant and Persistent Reduction in Blood Pressure with CVRx® Rheos® Hypertension Therapy



Data Presented at Hypertension Berlin 2008 Congress

Pivotal Rheos Trial in Progress

Minneapolis and Berlin – June 18, 2008 – The first available two-year data from the European clinical trial evaluating the Rheos® Hypertension (HT) System were presented today at Hypertension Berlin 2008. Developed by U.S.-based CVRx, Inc., the Rheos HT System is the only implantable medical device designed to control hypertension, or high blood pressure. Worldwide, hypertension is a leading and growing cause of heart and kidney disease, stroke and death. The Rheos HT System could provide a new treatment option for the millions of people who cannot control their hypertension with medications. The device activates the body's own system for regulating blood pressure.

“We are excited to see a sustained reduction in blood pressure after two years of Rheos HT Therapy – a major milestone in the evaluation of our novel treatment approach,” said Nadim Yared, CVRx president and chief executive officer.

“Hypertension is a complex condition, affecting multiple physiological functions. The early data on improved heart function and preserved kidney function also presented at this conference are encouraging, and we are hopeful Rheos HT Therapy may help prevent serious, costly conditions related to hypertension. Our Rheos Pivotal trial is assessing the safety and clinical efficacy of Rheos HT System and is well underway.”

The clinical data from the Device-Based Therapy of Hypertension (DEBuT-HT) study (Abstract No. OS17/3) were presented at Hypertension Berlin 2008, a joint congress held in Berlin of the 18th Scientific Meeting of the European Society of Hypertension and the 22nd Scientific Meeting of the International Society of Hypertension. Of the 45 patients enrolled in this study, 16 patients from four European centers have completed two years of Rheos HT Therapy. Blood pressure measurements were taken in the clinic and after two years showed:

- Systolic blood pressure was reduced by an average of 35 mmHg (191 mmHg vs. 156 mmHg); and
- Diastolic blood pressure was reduced by an average of 24 mmHg (116 mmHg vs. 92 mmHg).

Similar results were found at three months and one year of Rheos HT Therapy. Patients remained on background medical therapy during the trial. During the two-

(more)



year study period, the average number of antihypertensive medications remained stable.

A drop in systolic blood pressure of at least 20 mmHg was achieved in 12 of the 16 patients (75 percent). The Rheos implants were well tolerated, and there were no unanticipated adverse events related to the system or procedure. Further information on these study results can be found on the CVRx Web site at www.cvr.com.

Peter de Leeuw, professor of medicine and hypertension at the University of Maastricht in The Netherlands, is the leading enroller in the DEBuT-HT study. The 16 patients included in the two-year results were from the following clinical trial sites: the University Hospital Maastricht and Cardiovascular Research Institute Maastricht, Maastricht, The Netherlands; University Hospital, Inselspital Bern, Bern, Switzerland; Humboldt University Charité Campus Buch, Berlin; and Heart and Diabetes Center North Rhine Westphalia, Bad Oeynhausen, Germany.

Additional Rheos Data Presented at Hypertension 2008

Additional data from the DEBuT-HT study and U.S. Rheos feasibility study were presented in two poster sessions at Hypertension 2008. These studies showed early signs that the Rheos HT System can improve heart function and preserve kidney function.

- Heart function was notably improved among the 16 patients who completed one year of Rheos HT Therapy (Abstract No. PS33/THU/24). Blood pressure was reduced significantly, and left ventricular hypertrophy (LVH) significantly regressed. LVH, a process in which the heart becomes enlarged and does not work efficiently, increases the risk of heart attacks, heart failure and sudden cardiac death and regression of LVH reduces these risks.
- The University of Maastricht studied the effects of the Rheos HT Therapy on kidney function (Abstract No. PS32/WED/63) among their 12 patients who received therapy for one year. In this group, the Rheos HT Therapy was shown to help preserve kidney function over this time period. High blood pressure increases the risk and progression of kidney disease.

U.S. Rheos Pivotal Trial in Progress

CVRx received investigational device exemption (IDE) approval from the FDA to begin the Rheos Pivotal Trial to evaluate the safety and effectiveness of the Rheos HT System. The trial is enrolling 300 patients at multiple clinical sites in the United States and in Europe. Prospective patients can call (888) 8BP-RISK (827-7475) or visit www.bloodpressuretrial.com, to learn more about the clinical trial.

(more)



The Rheos HT System: Working with the Body's Own Mechanisms

The Rheos HT System uses CVRx patented Baroreflex Activation Therapy™ (BAT™) technology that is designed to electrically activate the carotid baroreceptors, the body's natural blood pressure sensors. When the baroreceptors are activated, signals are sent through neural pathways to the brain and interpreted as a rise in blood pressure. The brain works to counteract this perceived rise in blood pressure by sending signals to other parts of the body (heart, blood vessels and kidneys) to lower high blood pressure.

The Rheos HT System includes the following components:

- A small pulse generator that is implanted under the collar bone;
- Two thin lead wires that are implanted at the left and right carotid arteries and connect to the pulse generator; and
- The Rheos Programmer System, an external device used by doctors to non-invasively regulate the activation energy from the generator to the lead wires.

About Hypertension

Hypertension causes an estimated one in eight deaths worldwide.¹ In the United States alone, high blood pressure affects approximately 73 million people.¹ Approximately 25 percent of people with hypertension cannot control their high blood pressure, despite the use of multiple medications.^{2,3} Each incremental increase of 20 mmHg in systolic blood pressure or 10 mmHg in diastolic blood pressure above normal levels is associated with a two-fold increase in death rates from stroke, coronary heart disease and other vascular causes.

Editor's Note: Blood pressure is typically recorded as two numbers - the systolic pressure (top number) over the diastolic pressure (bottom number). The systolic pressure is the pressure of blood in the vessels when the heart contracts. Diastolic pressure is the pressure of the blood between heartbeats, when the heart is at rest and is refilling.

About CVRx, Inc.

CVRx, Inc., is a private company founded in 2001 and headquartered in Minneapolis, Minnesota U.S.A. Its senior management and technical teams have many years of experience commercializing implantable medical devices. For more information, visit www.cvr.com.

CVRx Contacts:

John Brintnall
Chief Financial Officer
jbrintnall@cvrx.com
Phone: 763.416.2853

Mary McGrory-USset
Corporate Communications
mmcgroryusset@comcast.net
Phone: 651.308.8225

(more)

CVRx, Inc.
June 18, 2008
Page 4



CVRx, Inc.
9201 West Broadway Avenue
Suite 650
Minneapolis, MN 55445
www.cvr.com

Padilla Speer Beardsley:

Nancy Johnson: 612-455-1745, 612-812-7568 cell / njohnson@psbpr.com
Nick Banovetz: 612-455-1705, 651-815-5999 cell / nbanovetz@psbpr.com

Footnotes:

¹ Heart Disease and Stroke Statistics. American Heart Association – 2008 Update.

² Lancet 2002;360:1903-1913.

³.JAMA 2003;289:2560-2572.

CAUTION: CVRx Rheos System is an investigational device and is limited by Federal (or United States) law to investigational use only.

CVRx, Rheos, Baroreflex Activation Therapy and BAT are trademarks of CVRx, Inc.

© CVRx, Inc. 2008. All rights reserved.

###