

News Release

Clinical Data Show CVRx® Rheos® Therapy Improved Heart Structure and Function in Early-Stage Heart Failure Patients



Data Shown as Poster at Heart Failure Society of America Meeting

Minneapolis and Toronto – Sept. 23, 2008 – Clinical data on the use of the CVRx® Rheos® System in treating early-stage heart failure patients shows Rheos Therapy significantly improved heart structure and function. John D. Bisognano, M.D., Ph.D., associate professor of medicine at the University of Rochester School of Medicine and Dentistry, New York, presented the data in a Sept. 22 poster session at the Heart Failure Society of America (HFSA) 12th Annual Scientific Meeting in Toronto. In heart failure patients, the heart becomes enlarged and functions inefficiently, increasing the risk of death and poor quality of life. Reducing heart size lowers these risks.

Clinical data presented as a poster at HFSA showed that continuous use of Rheos Therapy in early-stage heart failure patients remodels cardiac structure and improves heart function. The Rheos System was implanted in 18 patients at five medical centers in Europe and the United States. The patients had early-stage heart failure and high blood pressure, and were on optimal medication levels. After one year of Rheos therapy, left ventricular mass and left atrial dimension were reduced toward normal levels. In addition, blood pressure was lowered.

“We believe the Rheos System can have significant therapeutic value in heart failure patients,” said Dr. Bisognano. “The current clinical trial evaluating the Rheos System will help us further understand how Rheos Therapy addresses heart failure.” The first study evaluating Rheos Therapy in diastolic heart failure patients has begun in Europe.

“With one year of Rheos Therapy, the improvements in cardiac structure and function were significant in heart failure patients, and have not been seen with aggressive medical therapy currently available,” said Nadim Yared, CVRx president and chief executive officer. “We are excited about the possible clinical benefits of Rheos Therapy as a new approach to treating heart failure patients. With our recent financing, we have the resources to launch clinical research initiatives for the use of Rheos Therapy in heart failure patients. Heart failure represents a large unmet clinical need and a significant market opportunity for our company.”

CVRx, Inc., a private company based in Minneapolis, initially evaluated the Rheos System as a treatment for hypertension or high blood pressure. Many patients enrolled in early clinical evaluations of the Rheos System suffered from hypertension *and* had abnormal heart structure and function. Both conditions improved with Rheos Therapy. Worldwide, hypertension and heart failure are growing and leading causes

of death. The Rheos System could provide a new treatment option for millions of people who cannot control these conditions with medications.

The Rheos System: Working with the Body's Own Mechanisms to Reduce High Blood Pressure and Treat Heart Failure

The Rheos System uses the CVRx-patented Baroreflex Activation Therapy™ technology that is designed to activate the carotid baroreceptors, central components of the body's natural cardiovascular regulation system. 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) that relax the blood vessels and inhibit the production of stress-related hormones. These changes enable the heart to increase blood output, while maintaining or reducing its workload, thereby reducing blood pressure when it is elevated and alleviating the symptoms of heart failure.

The Rheos 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 connected to the pulse generator; and
- The Rheos Programmer System, an external device used by doctors to noninvasively regulate the activation energy from the generator to the lead wires.

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 5.2 million adults. Overall, heart failure is associated with a four-fold increased risk in death and a six to nine times increased risk of sudden cardiac death. The estimated direct and indirect costs of heart failure total \$34.8 billion annually in the United States.¹

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.

U.S. Rheos Hypertension 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 System in treating hypertension. 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.

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 is headquartered in Minneapolis. For more information, visit www.cvr.com.

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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.

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