

## News Release

### **CVRx<sup>®</sup>, Inc. Receives CE Mark Approval for Rheos<sup>®</sup> Baroreflex Hypertension Therapy<sup>™</sup> System**

**Minneapolis – October 31, 2007** – CVRx, Inc., a private medical device company, has received CE Mark approval for its Rheos<sup>®</sup> Baroreflex Hypertension Therapy<sup>™</sup> System, the only implantable device designed to control hypertension or high blood pressure. The system was approved for marketing in Europe based on clinical studies conducted in Europe and the United States.

“Receiving CE Mark approval is an important milestone for our company,” said Nadim Yared, CVRx president and CEO. “Currently, we are focused on advancing the Rheos Pivotal Trial in the United States. Patient enrollment in the Rheos Pivotal Trial is under way, and we expect outcomes from this study to support our Pre-Market Approval (PMA) application to the FDA.”

Recently published abstract results in the *Journal of Hypertension* showed a significant decrease in blood pressure with the Rheos System at 12 months. One-year results from 13 patients showed a 39 mmHg average decrease in systolic blood pressure and a 26 mmHg average decrease in diastolic blood pressure.<sup>1</sup>

#### **The Rheos Pivotal Trial and Rheos System**

CVRx received investigational device exemption (IDE) approval from the FDA to begin the Rheos Pivotal Trial that is evaluating the safety and effectiveness of the Rheos System. The trial is enrolling 300 patients at multiple clinical sites in the United States and in Europe. Visit [www.rheosstudy.com](http://www.rheosstudy.com) or call (866) 543-6434 to learn more about the Rheos Pivotal Trial and participant qualifications.

The Rheos System provides a “physiological rational” method to reduce blood pressure. The system’s proprietary technology uses the body’s own natural blood pressure regulation system (baroreflex) to control blood pressure. The Rheos System includes:

- 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.

The system electronically activates the baroreflex, which sends signals to the brain suggesting a blood pressure increase. Then, the brain acts to lower blood pressure by sending signals to various parts of the body to reduce blood pressure, including the blood vessels, heart and kidneys.

(more)

## **Hypertension: The Need for a New Treatment Option**

High blood pressure, also referred to as hypertension, affects about 65 million people in the United States alone.<sup>2</sup> Hypertension is estimated to cause one in every eight deaths worldwide. 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. Approximately 25 percent of people with hypertension cannot control their high blood pressure, despite the use of multiple medications.<sup>3,4</sup>

### **About CVRx, Inc.**

CVRx, Inc., is a private company founded in 2001 and headquartered in Minneapolis. Its senior management and technical teams have many years of experience commercializing implantable medical devices. For more information on CVRx visit [www.cvr.com](http://www.cvr.com).

### **Footnotes:**

<sup>1</sup>Scheffers I, Schmidli J, Kroon AA, et al. Sustained blood pressure reduction by baroreflex hypertension therapy with a chronically implanted system: Long-term data from the Rheos DEBuT-HT study in patients with resistant hypertension. *Journal of Hypertension* 2007;25 (Suppl 2):S141-142.

<sup>2</sup>Heart Disease and Stroke Statistics. American Heart Association – 2007 Update.

<sup>3</sup>U.S. Renal Data System. USRDS 2003 Annual Data Report. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2003.

<sup>4</sup>Prospective Studies Collaboration. Age-specific relevance of usual blood pressure to vascular mortality: a meta-analysis of individual data for one million adults in 61 prospective studies. *Lancet* 2002;360:1903-1913.

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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