CVRx Announces First Patient Enrollment in BENEFIT-HF, a Landmark Heart Failure Trial Evaluating Barostim in Significantly Expanded Population

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MINNEAPOLIS, May 04, 2026 (GLOBE NEWSWIRE) -- CVRx, Inc. (NASDAQ: CVRX), a medical device company focused on developing, manufacturing and commercializing innovative neuromodulation solutions for patients with cardiovascular diseases, today announced the enrollment of the first patient in the landmark BENEFIT-HF trial at North Central Heart - a division of the Avera Heart Hospital, in Sioux Falls, S.D. by Dr. Orvar Jonsson.

BENEFIT-HF is expected to be one of the largest therapeutic cardiac device trials ever performed in heart failure, enrolling 2,500 patients at approximately 150 centers in the United States and Germany. The prospective, randomized, controlled, multicenter trial is supported by CMS Category B IDE coverage and designed to evaluate all-cause mortality and heart failure decompensation events in a significantly expanded heart failure population.

“We are honored to enroll the first patient in the BENEFIT-HF trial,” said Dr. Orvar Jonsson, North Central Heart - a division of the Avera Heart Hospital. “This study will evaluate Barostim therapy in a broader population of patients who remain symptomatic despite optimized guideline-directed medical therapy, generating important data that will further define Barostim’s position in the heart failure continuum.”

“Achievement of this early milestone reflects tremendous excitement in the healthcare community regarding this landmark trial, and strong execution by the CVRx team in partnership with BENEFIT-HF investigators,” said Kevin Hykes, President and Chief Executive Officer of CVRx. “We are proud to collaborate with leading physicians in development of such meaningful clinical evidence, and excited to further characterize the patient benefits of Barostim therapy that we believe will drive long-term adoption.”

The BENEFIT-HF trial is expected to continue through 2032. If successful, the Trial could expand the indicated patient population for Barostim by approximately three times, significantly broadening access to the therapy.

About CVRx, Inc.
CVRx is a commercial-stage medical device company focused on developing, manufacturing and commercializing innovative neuromodulation solutions for patients with cardiovascular diseases. Barostim™ is the first medical technology approved by FDA that uses neuromodulation to improve the symptoms of patients with heart failure. Barostim is an implantable device that delivers electrical pulses to baroreceptors located in the wall of the carotid artery. The therapy is designed to restore balance to the autonomic nervous system and thereby reduce the symptoms of heart failure. Barostim received the FDA Breakthrough Device designation and is FDA-approved for use in heart failure patients in the U.S. It has been certified as compliant with the EU Medical Device Regulation (MDR) and holds CE Mark approval for heart failure and resistant hypertension in the European Economic Area. To learn more about Barostim, visit www.cvrx.com.

Forward-Looking Statements
This press release contains forward-looking statements, including statements regarding the expected timing, enrollment, scope, and outcomes of the BENEFIT-HF clinical trial, potential expansion of the Barostim indication, and anticipated benefits of Barostim therapy. These forward-looking statements speak only as of the date of this press release and are subject to a number of known and unknown risks, uncertainties and assumptions, including, but not limited to, our expectations regarding enrollment; the resulting impact on our addressable market; impacts on adoption and regulatory approvals resulting from additional long-term clinical data about our product, including those resulting from the BENEFIT-HF clinical trial; and other important factors that could cause actual results, performance or achievements to differ materially from those that are found in “Part I, Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2025, as such factors may be updated from time to time in our other filings with the Securities and Exchange Commission. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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