CVRx Announces Initiation of BENEFIT-HF, a Landmark Heart Failure Trial Evaluating Barostim in Significantly Expanded Population

January 22, 2026

Study is Expected to Be One of the Largest Therapeutic Cardiac Device Trials in Heart Failure Ever Performed, and is Supported by CMS Category B IDE Coverage

MINNEAPOLIS, Jan. 22, 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 initiation of the BENEFIT-HF clinical trial, a landmark randomized study supported by CMS Category B IDE coverage and designed to evaluate the impact of Barostim™ in a significantly expanded heart failure population.

Barostim™ is an implantable device that delivers electrical signals to baroreceptors located on the carotid artery, increasing baroreflex signaling, rebalancing the autonomic nervous system, and improving heart failure symptoms. Barostim™ received FDA approval in 2019 following its designation under the FDA's Breakthrough Devices Program and is now commercially available in both the U.S. and Europe.

The BENEFIT-HF trial is expected to be one of the largest therapeutic cardiac device trials ever performed in heart failure, randomizing 2,500 patients in approximately 150 centers in the United States and Germany. The primary endpoint will be a composite of all-cause mortality and heart failure decompensation events. Enrollment is expected to begin in the first half of 2026.

The BENEFIT-HF trial is designed to evaluate Barostim in patients with heart failure who:

- Remain symptomatic after receiving optimized guideline-directed medical and device therapies (GDMT)
- Have a left ventricular ejection fraction (LVEF) <50% (*compared to the current Barostim indication of ≤35%)*
- Have NT-proBNP levels <5,000 pg/mL (*compared to the current Barostim indication of <1,600 pg/mL)*

If successful, the BENEFIT-HF trial could expand the indicated patient population for Barostim approximately three times, significantly broadening access to this proven neuromodulation-based approach to heart failure management.

Importantly, the Centers for Medicare & Medicaid Services (CMS) has approved Category B IDE coverage for the BENEFIT-HF clinical trial under IDE regulations (42 CFR § 405 Subpart B), effective January 1, 2015, supporting patient access to therapy during the trial period and reinforcing the trial's feasibility at scale.

"The BENEFIT-HF trial represents an important evolution in our clinical strategy to treat patients with heart failure," said Philip Adamson, MD, Chief Medical Officer of CVRx. "Our earlier BeAT-HF trial provided robust clinical insights that showed clear improvement in symptoms and functional status within a segment of the heart failure population. BENEFIT-HF is now designed to rigorously evaluate morbidity and mortality in a broader heart failure population already being treated with standard of care."

"Heart failure remains one of the most significant unmet needs in cardiovascular medicine," said Kevin Hykes, President and Chief Executive Officer of CVRx. "Launching a trial of this magnitude demonstrates our leadership in the field and our commitment to advancing the science of heart failure care, building upon the outstanding patient outcomes experienced by Barostim patients in both clinical studies and real-world experience. We are seeing tremendous excitement from physicians and clinical partners for the BENEFIT-HF trial and the role Barostim may play in treating a much broader heart failure population."

CVRx plans to provide additional details regarding trial design, site activation, and enrollment timelines on its February earnings release call.

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 of our addressable market 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, 2024 and "Part II, Item 1A. Risk Factors" in our Quarterly Report on Form 10-Q for the quarter

ended September 30, 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.

Investor Contact:
Mark Klausner or Mike Vallie
ICR Healthcare
443-213-0501
ir@cvrx.com

Media Contact:
Emily Meyers
CVRx, Inc.
763-416-2853
emeyers@cvrx.com