Totality of Evidence from BeAT-HF Study Shows CVRx's Barostim Provides Long-term Benefits for Patients with Heart Failure

March 21, 2023

MINNEAPOLIS, March 21, 2023 (GLOBE NEWSWIRE) -- CVRx, Inc. (NASDAQ: CVRX) ("CVRx"), a commercial-stage medical device company focused on developing, manufacturing and commercializing Barostim™, an innovative extravascular implantable neuromodulation device for patients with cardiovascular diseases, announced detailed preliminary results of the post-market phase of the BeAT-HF trial at the second annual Technology and Heart Failure (HF) Therapeutics (THT) conference on Tuesday, March 21, 2023. These results are being presented by Dr. Michael Zile, Professor of Cardiology at the Medical University of South Carolina (MUSC).

Highlights of the data presented by Dr. Zile include:

- **Safety - Major Adverse Neurological or Cardiovascular (MANCE) system or procedure-related event-free rate**
  - MANCE-free rate of 97% (p<0.001)
- **Long-term symptom improvement for Barostim Baroreflex Activation Therapy (BAT) vs. Control:**
  - 6 Minute Hall Walk improved by 44 meters at 12 months (nominal p<0.001)
  - Quality of Life improved by 10 points in Minnesota Living with Heart Failure Questionnaire at 24 months (nominal p<0.001)
  - NYHA Class improved in 27% more BAT patients at 24 months (nominal p<0.001)
- **Mortality (cardiovascular death, LVAD, heart transplant) and morbidity (HF hospitalizations, ER visits) – primary endpoint**
  - No statistically significant difference [Rate Ratio 0.94, (95% Confidence Interval 0.57, 1.57); p=0.82]
- **All-cause mortality (all-cause death, LVAD, heart transplant)**
  - 34% relative reduction in BAT vs. Control [Hazard Ratio 0.66 (95% CI 0.44, 1.007); nominal p=0.054]
- **Hierarchical composite of cardiovascular death, LVAD, heart transplant, HF hospitalization, and Quality of Life using Win Ratio**
  - Win Ratio of 1.26 favored BAT vs. Control [95% CI 1.02, 1.58; nominal p=0.04]

Dr. Zile's presentation concludes that the "Totality of evidence indicates that BAT is a safe, effective and durable treatment for patients with heart failure with reduced ejection fraction." The slides from Dr. Zile's featured presentation, as well as key slides that will be presented as part of the CVRx-sponsored THT symposium, can be found at ir.cvrx.com.

"We are happy to see the significant long-term data that favored Barostim," added Nadim Yared, President and CEO of CVRx. "Interest and adoption of the therapy continue to expand based on the previously-approved claims, and now we look forward to submitting this new data to the FDA to pursue expanded labeling for Barostim. We are forever grateful to the patients, investigators, nurses, and research staff involved in the study."

The full results of BeAT-HF, including a number of additional analyses and endpoints, will be submitted by the executive steering committee for publication in one or more peer-reviewed journals. CVRx anticipates that regulatory submission to the FDA for expanded labeling will be made in the coming months.

About CVRx, Inc.

CVRx is a commercial-stage medical device company focused on the 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. Baroreceptors activate the body's baroreflex, which in turn triggers an autonomic response to the heart. 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 also received the CE Mark 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 within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts are forward-looking statements, including statements regarding our future financial performance, our anticipated growth strategies, anticipated trends in our industry, our business prospects and our opportunities, including specifically those related to potential new indications, labelling or marketing opportunities, our continued review and analysis of trial data and future business and financial impacts. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "outlook," "guidance," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words.

The forward-looking statements in this press release are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. 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, uncertainties related to obtaining regulatory approvals, further analysis and understanding of clinical trial data, physician and patient adoption, and other important factors that could cause actual results, performance or achievements to differ materially from those projected in the forward-looking statements that are found in “Part I, Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2022, 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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