CVRx announces availability of additional data supporting long-term benefits of Barostim

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BeAT-HF trial data published in the European Journal of Heart Failure and new abstracts presented at THT conference

MINNEAPOLIS, Minn., April 15, 2024 (GLOBE NEWSWIRE) -- CVRx, Inc. (NASDAQ: CVRX) ("CVRx"), a commercial-stage medical device company, announced today the availability of additional data, including the publication of results of the post-market phase of the BeAT-HF trial in the European Journal of Heart Failure. These data highlight long-term sustained benefits of Barostim in heart failure patients with reduced ejection fraction.

"Publication of these data from the post-market phase of BeAT-HF in this prestigious peer-reviewed journal allows for more effective dissemination of the long-term results of this important trial and the positive symptomatic impact of Barostim on patients with heart failure," said Kevin Hykes, President and CEO of CVRx. "Additionally, we are pleased at the favorable physician response to new abstracts released at THT in Boston on March 5, 2024, that show a reduction in additional heart failure interventions in patients with Barostim, as well as specific patient-centered benefits at long-term follow-up."

The manuscript is available online at the European Journal of Heart Failure website. CVRx previously announced some of these data as part of expanded labeling granted by FDA on December 23, 2023. The key benefits of Barostim contained in the manuscript include the following:

- There was not a statistically significant difference in the primary endpoint of CV death and HF hospitalization, demonstrating that the benefits of the therapy do not increase the long-term risk of harm to patients
- Patients receiving Barostim + guideline-directed medical therapy (GDMT) had sustained and significant symptomatic improvements (6 minute hall walk, quality of life and NYHA class) at up to 2 years versus those patients receiving GDMT alone
- Patients receiving Barostim + GDMT had a 34% reduced likelihood of all-cause death or the need for left ventricular assist device (LVAD) implantation or heart transplant, suggesting a favorable effect of Barostim therapy

Additionally, two new post-hoc analyses of the BeAT-HF trial data, presented on March 5, 2024 at Technology in Heart Failure Therapeutics (THT) 2024 in Boston, suggest additional important benefits of Barostim.

- Dr. William Abraham of the Ohio State Wexner College of Medicine presented analysis showing that patients in the trial with Barostim + GDMT had a 74% reduced risk of receiving advanced heart failure interventions (transplant, LVAD, CCM, CRT or CardioMEMS) at long-term follow-up versus patients on GDMT alone. See more details at TCTMD.
- Dr. JoAnn Lindenfeld of Vanderbilt University presented analysis showing that patients with Barostim + GDMT had sustained and significant improvements in quality-of-life scores (MLWHF and EQ-5D) and many subdomains of these scores (e.g., reductions in shortness of breath, fatigue, depression and improvements in self-care, mobility and pain, etc.) versus patients on GDMT alone. See more details at TCTMD.

"We are grateful to the BeAT-HF executive steering committee and the many investigators involved in the trial for their dedication to advancing the science supporting this therapy. We look forward to the generation of additional evidence about Barostim from the BeAT-HF trial, as well as from real-world experience through our REBALANCE post-market registry and investigator-initiated research," said Hykes.

About CVRx, Inc.
CVRx is focused on the development and commercialization of the Barostim™ System, the first medical technology approved by FDA that uses neuromodulation to improve the symptoms of 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.

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