



## CVRx receives FDA approval for expanded labeling of Barostim

December 26, 2023

### U.S. annual market opportunity increases based on real world adoption and strength of long-term BeAT-HF data

MINNEAPOLIS, Dec. 26, 2023 (GLOBE NEWSWIRE) -- [CVRx, Inc.](#) (NASDAQ: CVRX) ("CVRx"), a commercial-stage medical device company, announced today that the U.S. Food and Drug Administration (FDA) has approved revised Instructions For Use (IFU) for Barostim incorporating key long-term clinical data from the BeAT-HF randomized clinical trial.

"We are very pleased to receive this important validation from FDA of the long-term results of the post-market phase of the BeAT-HF clinical trial and excited we can now share this data with physicians and patients," said Nadim Yared, President and CEO of CVRx. "We remain grateful to all patients, investigators, research teams, the executive steering committee and FDA personnel, for supporting our efforts to conduct this landmark study over seven years, including the difficulties encountered during the COVID-19 pandemic."

### Labeling Update

The updated Indications statement for Barostim in the IFU now reads:

Barostim is indicated for patients who are NYHA Class III or Class II (who had a recent history of Class III) despite treatment with guideline-directed medical therapies (medications and devices), have a left ventricular ejection fraction of  $\leq 35\%$ , and a NT-proBNP  $<1600$  pg/ml.

Barostim delivers Baroreflex Activation Therapy to improve patients' heart failure functional status, six-minute hall walk, and quality of life.

The revised Clinical Summary section of the IFU now includes the primary endpoint results, the 6, 12 and 24 month symptomatic data, the win ratio, and the all-cause mortality data. The Clinical Summary concludes:

In summary, the primary safety endpoint in the Pre-Market Phase was previously met and confirmed in the Post-Market Phase. In the Pre-Market Phase, all effectiveness endpoints were previously met, demonstrating 6-months improvements in 6MHW, quality of life, NYHA Class and NT-proBNP. The Post-Market Phase effectiveness primary endpoint of CV death and HF hospitalization was not met. Additional Post-Market Phase effectiveness analyses (Win Ratio, freedom from all-cause mortality) suggested a favorable effect of Barostim therapy. The totality of the 6, 12 and 24-month data demonstrated symptomatic improvements for heart failure patients who are NYHA Class III or Class II (who had a recent history of Class III) despite treatment with guideline-directed therapies and have a left ventricular ejection fraction  $\leq 35\%$  and a NT-proBNP  $<1600$  pg/ml.

The revised IFU document can be found at [www.cvr.com/ifu](http://www.cvr.com/ifu), and the Clinical Summary section of that IFU can be found at pages 24 to 39.

### Annual Market Opportunity Update

Our estimate of the U.S. annual market opportunity for Barostim has been revised to increase the number of patients considered by physicians based on this new long-term safety and efficacy data as well as our commercial experience, and to account for the new reimbursement assignment for Barostim. We believe the U.S. annual market opportunity is now \$2.2 billion, or 76,000 new patients, as compared to our earlier estimate of \$1.4 billion, or 55,000 new patients, representing increases of approximately 60% and 38%, respectively.

### 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.cvr.com](http://www.cvr.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 the expected market for Barostim. 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, but not limited to, our ability to demonstrate to physicians and patients the merits of our Barostim 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, 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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