First Patient Treated with BioVentrix® Revivent System in RELIVE Trial at Saint Luke's Mid America Heart Institute

Pivotal RELIVE Trial Is Evaluating the Safety and Efficacy of BioVentrix's Revivent System in the Treatment of Patients Who Have Experienced Heart Failure

BioVentrix, Inc.

MANSFIELD, MA, UNITED STATES, November 3, 2025 /EINPresswire.com/ -- BioVentrix, Inc., a private clinical-stage medical device company specializing in left ventricular function restoration following heart failure, today announced the completion of treatment of its first patient in its pivotal RELIVE (Randomized Evaluation of Less Invasive Ventricular Enhancement) clinical trial at Saint Luke's Mid America Heart Institute in Kansas City, Missouri.

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> *Andrew Kao, MD, advanced heart failure cardiologist.*

BioVentrix's proprietary Revivent System, which is being studied in the RELIVE trial, is designed to restore left ventricular function in heart failure patients with so-called "reduced ejection fraction" (a measure of the blood pumped by the left ventricle of the heart) and extensive left ventricular scarring. Jessica Heimes, DO, cardiothoracic surgeon at Saint Luke's Mid America Heart Institute and associate professor of surgery at the University of Missouri-Kansas City School of Medicine, performed the first procedure on a patient with symptomatic ischemic heart failure, characterized by damage to the left side of the heart and left ventricular scarring from a prior heart attack.

Heart attacks can lead to scarring and adverse remodeling of heart tissue, which may compromise the heart's ability to pump effectively and increase the risk of heart failure – a condition that poses serious health challenges. In the United States, an estimated 28,000 patients each year develop large anterior scars following a heart attack, potentially qualifying

them for investigational treatments like the Revivent procedure.

“Heart failure can stem from many different causes,” said Andrew Kao, MD, advanced heart failure cardiologist at Saint Luke’s Mid America Heart Institute, and professor of medicine, University of Missouri-Kansas City School of Medicine. “For the right patient, treatment with the Revivent System could represents a valuable option. While all cardiac surgeries come with challenges, this approach offers a remarkably straightforward solution to a complex problem.”

The RELIVE Trial is a prospective, randomized, multi-center, dual-arm pivotal study of the BioVentrix Revivent System. The trial aims to evaluate the safety and efficacy of the Revivent System in restoring left ventricular function in heart failure patients with reduced ejection fraction and extensive left ventricular scarring. The less invasive Revivent System has previously received Breakthrough Therapy Designation by the U.S. Food and Drug Administration.

“As we advance our pivotal RELIVE Trial, this milestone marks the first of many patients we expect to treat at Saint Luke’s and across our other trial locations with this innovative therapy,” said Steve Chartier, President and Co-CEO of BioVentrix, Inc. “We believe the Revivent System holds significant promise—not only for improving patient outcomes, but also for supporting physicians, hospitals, and payers. We are proud to collaborate with the exceptional cardiology and cardiac surgery teams at Saint Luke’s, and we are excited to continue advancing the trial and remain committed to delivering meaningful clinical results.”

About the Revivent System

The BioVentrix Revivent System is designed to support a less invasive procedure to treat a dilated left ventricle of patients with ischemic heart failure with reduced ejection fraction (HFrEF) and extensive left ventricular scar, who have a suboptimal response to guideline-directed medical therapy. The procedure uses myocardial micro-anchor implants to reconstruct the dilated left ventricle to produce a more efficient chamber. Prior trials showed statistical significance with a subpopulation for similar endpoints to those that will be assessed in the RELIVE Trial. The Revivent System received the CE Mark in 2016.

About BioVentrix

BioVentrix, Inc. is a medical device company focused on developing innovative therapies to restore heart function and enhance the quality of life for patients suffering from advanced heart failure. Its solutions offer heart failure specialists new treatment options aimed at improving left ventricular function which may increase cardiac ejection fraction. The company’s flagship product, the Revivent System, is currently undergoing evaluation in the RELIVE Study, a pivotal clinical trial in the United States, and is in the early stages of commercialization across Europe.

unauthorized use is expressly prohibited.

Investigational Device. The Revivent System is limited to Investigational Use Only in The United States.

Cautionary Note Regarding Forward-Looking Statements

Certain statements in this press release are forward-looking, which may be identified by the use of words such as “anticipate,” “expect,” “believe,” “forecast,” “aim,” “estimate” and “intend,” among other similar words. These forward-looking statements are based on BioVentrix’s current expectations. and actual results could differ materially and adversely from what is contemplated by the forward-looking statements. There are a number of risks and uncertainties that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the timing for enrollment in and outcomes from our clinical trials and ongoing FDA and other regulatory requirements, and interpretation of trial data by the FDA. As with any medical device under development, there are significant risks in the development, testing, regulatory approval, and commercialization of new products. Except as expressly required by law, BioVentrix does not undertake an obligation to update or revise any forward-looking statement. All of BioVentrix’s forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date hereof.

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