

FOR IMMEDIATE RELEASE

BioVentrix Releases Results of Revivent™ Impact on Mitral Regurgitation

Retrospective sub-study demonstrates impact of ventricular reshaping on mitral regurgitation patients.

San Ramon, Calif., November 23, 2015 — <u>BioVentrix</u>, announced today that it has completed an analysis of patients with mitral regurgitation who were treated with its Revivent ventricular volume reduction and reshaping technology. The Revivent system is a novel, less invasive therapy designed to treat patients suffering from ischemic cardiomyopathy heart failure. Mitral regurgitation (MR) affects 1.6-2.8 million people in the US¹ and is widespread in the ischemic heart failure population. An estimated 40 percent of patients with heart failure have a moderate-to-severe ischemic or functional form of MR which originates from ventricular dysfunction². Although less invasive therapies are currently utilized to treat the valvular and vascular components of heart failure, no proven therapy exists to address the ventricular origin of ischemic mitral regurgitation. BioVentrix investigated the impact of its Revivent therapy on this patient population in a retrospective sub-study analysis of its broader safety and efficacy trial in 7 EU centers.

In the sub study (n=29), it was found that 76 percent of patients with MR that were treated with Revivent had an improvement in mitral valve functionality³. Additionally, it was demonstrated that some patients that were preoperatively ineligible for other adjunctive mitral valve therapies could potentially be treated following the ventricular reshaping procedure offered by Revivent⁴.

"The discovery that Revivent can not only correct ventricular dysfunction through geometric reshaping but also potentially improve mitral valve performance is a significant finding for heart failure patients. Current technologies do not consistently or durably resolve ischemic mitral regurgitation" said Dr. Nina Wunderlich, Director of the Department of Non-Invasive Cardiology at the Darmstadt Cardiovascular Center, Germany. Dr. Wunderlich is a recognized expert in the field of mitral regurgitation. She is a frequent lecturer and prolific author who has published numerous articles on the topic. "This technology opens a whole new approach to the treatment of MR" she added.

With a large underserved market available, BioVentrix intends to expand its European clinical trial in the coming year to include a more focused evaluation of the use of Revivent to treat mitral regurgitation.

About the Revivent System and the LIVE Procedure

Placement of the Revivent System via the LIVE procedure obviates the need for more invasive surgery. Instead, small titanium anchors are placed along the outer surface of the heart and along one of the interior walls via a closed-chest, transcatheter approach. The anchors are then pulled toward one another, effectively excluding the scarred and non-functioning heart wall. Ventricular volume is immediately reduced as a result of the exclusion, by as much as 30-40 percent.⁵

Click here for corporate video with animation

#####

Contact: David Schickling, VP of Sales and Marketing, +1-925-830-1000

¹Perrault, L. et al., Optimal surgical management of sever ischemic mitral regurgitation: to repair or to replace? The Journal of Thoracic and Cardiovascular Surgery 2012:143:1396-1403.

²Patel, J. et al. Mitral regurgitation in patients with advanced systolic heart failure. Journal of Cardiac Failure 2004;10:285-91.

^{3,4}Revivent Data on file.

⁵Wechsler, A. et al., Clinical benefits twelve months after less invasive ventricular restoration operations without ventriculotomy. Annual meeting of the European Society of Cardio-Thoracic Surgery, 07 Oct. 2013, Vienna, Austria.