Favorable Patient Outcomes For Heart Failure Treatment Reported

Results from a clinical abstract to be presented at the TCT 2012 [1] (Transcatheter Cardiovascular Therapeutics), the annual scientific symposium of the Cardiovascular Research Foundation, show that patients with heart failure caused by scarring of the left ventricle (LV) from a previous heart attack, and treated with BioVentrix's Less Invasive Ventricular Enhancement [2] (LIVE) procedure, had significantly improved quality-of-life (QOL) scores at one-year follow-up.

BioVentrix's chief medical officer, Lon S. Annest [3], M.D., MBA, will present 12-month outcome measures from the company's first-in-man (FIM) clinical trial of its Revivent Myocardial Anchoring system [4] for use in LIVE [5]procedures. Thirty-two patients with ischemic cardiomyopathy, the most common cause of heart failure, underwent an open sternotomy approach. One-year follow-up data was obtained from twenty patients and showed an overall significant improvement in QOL measures (29 percent improvement from pre-operative measures). New York Heart Association Functional Class (NYHA FC) dropped from 2.5 to 1.0 (34 percent), and standardized six-minute walk test (6MWT) showed a 31 percent improvement.

Based on these clinically significant outcomes, BioVentrix [6] is developing a closed-chest, off pump transcatheter hybrid procedure to achieve the same results. This new technique may be of particular interest to patients who are too ill or fragile to undergo traditional surgery, as well as for cardiologists who have exhausted other minimally invasive treatment options for this patient population.

"We are very encouraged from the one-year follow-up results, as they show substantial improvement from pre-operative evaluation, adding to our growing data that reinforces the clinical benefits of the Revivent system [7] used during LIVE procedures," said Dr. Annest. "Our future hybrid procedure is based on the identical implant technology, which we believe will offer patients who are unable to lead a normal life, with an even less invasive procedure that fosters their return to basic activities, such as walking and routine tasks."

BioVentrix recently announced commencement of its Phase II, 50-patient study to evaluate the safety and efficacy of the Revivent system used during the LIVE procedure, taking place at up to 25 institutions throughout the European Union. Results from the first enrollment, a 58-year-old male with symptomatic heart failure, are very positive. Under the guidance of Louise Labrousse, M.D., Professor of Cardiovascular Surgeryat Hopital Haut-Lévêque in Bordeaux-Pessac, France, the patient was the first to undergo the LIVE procedure with an indwelling Internal Cardioverter Defibrillator (ICD). Initial results show that the LV end diastolic volume decreased by 45 percent, the LV end systolic volume decreased by 53 percent, and

ejection fraction improved from 26 percent to 36 percent. The patient was released from the ICU within two days of the LIVE procedure and released from the hospital within 10 days of undergoing treatment due to excellent progress in recovery.

Heart Failure [8] is a widespread disease with symptoms that include shortness of breath, exercise intolerance, swelling of the ankles from fluid retention and general fatigue caused by the inability of the heart to pump blood efficiently to meet the demands of the body. This leads to limited physical activity, loss of quality of life and decreased survival. Currently, open-heart surgical procedures are applied sparingly among such a compromised patient group due to its invasiveness.

About the Revivent System and LIVE Procedure The Revivent system [9] is comprised of a series of titanium anchor pairs, each consisting of an internal anchor and an external anchor, which are introduced by transmural catheters. Once the desired number of anchor pairs are positioned, a force gauge is used to control apposition, pulling the lateral LV wall toward the septum. This creates a fold of tissue that effectively excludes the non-functioning scar tissue created by a previous heart attack. The ventricle is restored to a more optimal, conical shape, thereby enhancing performance of the remaining myocardium, and ultimately improving quality of life.

Previously, reshaping of the ventricle in ischemic cardiomyopathy required an invasive procedure known as surgical ventricular restoration (SVR), performed with the use of cardiopulmonary bypass, where significant incisions into the heart muscle are made to excise the scarred, non-functioning ventricular tissue. The invasive nature of SVR limits the number of patients for whom the procedure may be performed due to the fragile nature of this patient population. In contrast, the LIVE procedure using the Revivent system is performed without the need of cardiopulmonary bypass or making incisions in the heart. The Revivent system may be used as a stand-alone procedure or concurrently during coronary artery bypass grafting.

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