BioVentrix Initiates Phase II Study of Revivent System for Less Invasive Heart Failure Treatment in Western Europe

The Associated Press

BioVentrix, the developer of minimally invasive therapies for the treatment of heart failure, today announced the initiation of a Phase II clinical trial to evaluate the safety and efficacy of its Revivent Myocardial Anchoring System for use in Less Invasive Ventricular Enhancement (LIVE) procedures in patients with heart failure. The Phase II study commenced in Western Europe under the guidance of Louis Labrousse, M.D., Professor of Cardiovascular Surgery, Hopital Haut-Lévêque, Bordeaux-Pessac, France.

"The results from our first LIVE procedure using the Revivent Myocardial Anchoring System on a 58-year-old male with symptomatic heart failure confirm the safety and efficacy of this novel technique," said Professor Labrousse. "The left ventricle (LV) end diastolic volume decreased by 45 percent and the LV end systolic volume decreased by 53 percent, while ejection fraction improved from 26 percent to 36 percent.

"Because this procedure was performed on a beating heart without the risks of a ventriculotomy or the need for cardiopulmonary bypass, the recovery of the patient is significantly faster. Our patient was released from ICU within two days of the LIVE procedure and released from the hospital within 10 days of undergoing treatment due to the excellent progress in recovery. Additionally, this was the first BioVentrix patient to be treated with an indwelling Internal Cardioverter Defibrillator (ICD). This further demonstrates that the Revivent technology can be applied to a broad spectrum of heart failure patients in various stages of treatment," continued Professor Labrousse.

The Phase II, 50-patient study will take place at up to 25 institutions throughout the European Union, and will be limited to patients whose heart failure is due to LV scar resulting from a previous heart attack. This condition is called ischemic cardiomyopathy, which is the most common cause of heart failure. It limits the ability of the LV to pump blood to the body because the scarred portion of the LV no longer contracts properly.

The primary safety endpoint will be an assessment of the overall rate of serious adverse events during a 12-month follow-up period, and the primary efficacy endpoint will be assessment of a measurable decrease in LV volume by either an echocardiogram or a cardiac magnetic resonance (CMR) exam at six months, and at one year.

"BioVentrix has clinically proven the benefits of LIVE using the Revivent system as evidenced by improved clinical outcomes from patients treated to date," said Tessa Yamut, vice president of regulatory and clinical affairs at BioVentrix. "In fact, data to be released later this month demonstrates that 12-month outcome measures show a clear trend in QOL improvement from pre-operative evaluation.

"Our Phase II study provides us the opportunity to broaden our clinical experience base amongst leading heart failure institutions throughout the European Union, as well as expand awareness of our promising, innovative technique," continues Yamut.

Earlier this year, BioVentrix presented six-month results of a Phase I trial demonstrating safety and feasibility of the Revivent system for use in LIVE procedures. Results from the 26-patient trial indicate that the BioVentrix approach is an impactful method of treating ischemic heart failure. LV volume reduction was accomplished in all 26 patients. Post-procedure follow-up included serial echocardiograms to measure the function of the LV, six-minute walk tests, New York Heart Association Functional Class (NYHA FC) assessment, and quality-of-life (QOL) questionnaires at one, three, six and 12 months.

Heart Failure 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 reduced 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. In Europe, nearly 40 percent of heart failure patients will die within one year of first hospitalization, and only 25 percent of men and 38 percent of women will survive more than five years following diagnosis(1,2).

Approximately 14 million people in Europe currently suffer from heart failure and this number is expected to increase to 30 million by the year 2020, according to the Study Group on Heart Failure Awareness and Perception in Europe (SHAPE). In addition, over 3.6 million new cases are reported each year in Europe and admission to hospitals with heart failure has more than doubled in the last 20 years. Heart failure in Europe is more common than most cancers, including breast, testicular, cervical and bowel cancers(3).

About the Revivent System and LIVE Procedure:The Revivent system 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.

About BioVentrix:BioVentrix is a privately held medical device company headquartered in San Ramon, Calif. U.S.A. Its mission is to improve and expand on the treatment of heart failure, primarily through the development of less invasive, catheter-based approaches. The company's proprietary systems are designed to offer a less invasive, accelerated recovery treatment that improves cardiac function by restoring the geometry and resulting function of the left ventricle, thereby improving a patient's quality of life. The company's clinical investigators include some of the world's leading surgeons and cardiologists. The BioVentrix system is an investigational device pending CE Mark. For more information, please visit: http://bioventrix.com.

(1) Blackledge HM, Tomlinson J, et al. Prognosis for patients newly admitted to hospital with heart failure: survival trends in 12 220 index admissions in Leicestershire 1993-2001. Heart 2003;89:615-620.

(2) Ho KK et al. Survival after the onset of congestive heart failure in Framingham Heart Study Subjects. Circulation 1993; 88:107-15.

(3) Stewart S et al. More malignant than cancer? Five year survival following a first admission for heart failure. The European Journal of Heart Failure 2001; 3:315-322.

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