BioVentrix receives FDA IDE Approval for its Pivotal Clinical Trial, ALIVE

SAN RAMON, Calif., May 31, 2016 – BioVentrix Inc., an emerging medical device company for less invasive treatment of heart failure (HF), today announced that it has received a U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) approval to initiate its pivotal clinical trial, named ALIVE (American Less Invasive Ventricular Enhancement). The trial is designed to demonstrate the safety and effectiveness of the Revivent TC™ TransCatheter Ventricular Enhancement System; a hybrid closed-chest transcatheter procedure to treat patients suffering from ischemic cardiomyopathy by reshaping and restoring the left ventricle (LV). This is accomplished by implanting micro-anchoring pairs in the LV to exclude scarred myocardium from the healthy tissue.

“Heart failure continues to be an epidemic and the BioVentrix technology fills a critical need here in the U.S. for ischemic patients,” said lead U.S. Principal Investigator Dr. Andrew Wechsler. “The current therapy, surgical ventricular reconstruction, is effective yet it is highly invasive and limited in terms of patients being able to withstand the procedure. This IDE approval provides another treatment option that physicians can consider when exploring the best therapy solution for heart failure patients,” continued Dr. Wechsler.

The ALIVE trial plans to enroll 120 patients at up to 20 sites nationwide with a primary endpoint analysis at 1 year. The trial endpoints include positive effects on volume reduction, ejection fraction, quality of life (QOL), New York Heart Association (NYHA) Class, 6 minute walk test, and rehospitalization. Admission rates following heart failure hospitalization remain high, with ≥ 50% patients readmitted to hospital within 6 months of discharge. Annually, over 1 million patients are hospitalized with a primary diagnosis of heart failure, accounting for a total Medicare expenditure exceeding $17 billion1.

“The Revivent TC system has recently demonstrated efficacy in clinical trials performed in the EU,” said Dr. Ryan Brown, Cardiologist and Vice President of Medical Affairs for BioVentrix. “This technology provides a less invasive means for LV scar reduction/exclusion in patients with prior myocardial infarction and LV dysfunction. Restoration of LV morphologic and volume characteristics in a less invasive manner, compared with current surgical ventricular restoration, will ideally avail this technology and procedural concept to a larger patient population,” continued Dr. Brown.

BioVentrix has shown in multiple clinical trials in Europe that the exclusion of scar tissue from the LV cavity in patients suffering from ischemic cardiomyopathy and heart failure symptoms results in substantial improvements in LV volume, NYHA Class, 6 minute walk tests, and Quality of Life2. Additionally, previous studies reported in the surgical literature have shown that a significant LV volume reduction conveys a survival benefit for treated patients3.

About the Revivent TC™ System and the LIVE™ (Less Invasive Ventricular Enhancement) Procedure

Placement of the Revivent TC™ 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, endovascular 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 percent1.

Click here for corporate video with animation

About the LIVE™ Procedure: The World’s Only Reshaping Left Ventricle Therapy

The LIVE™ procedure is based upon a well-defined law of physics called the law of Laplace, which describes the relationship between the radius and pressure of the LV, and its resulting wall tension. Increased wall tension is the underlying cause of LV enlargement, worsening heart failure symptoms and ultimately patient death. Reducing wall tension is key to preventing further LV enlargement and treats the progression of the disease. The Revivent TC™ System, placed via the LIVE procedure, is uniquely designed to directly reduce the LV radius, which in turn decreases wall tension and interrupts the ongoing, destructive process of heart failure.

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2 Wechsler, 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.