

## **BioVentrix to Exhibit Revivent™ System, which Surpasses Survival Benefit Threshold for Heart Failure Treatment, at European Heart Failure Congress**

The Associated Press

LISBON, Portugal--(BUSINESS WIRE)--May 22, 2013--BioVentrix, pioneer of the Less Invasive Ventricular Enhancement™ (LIVE™) procedure for the treatment of heart failure (HF), announced today that it will showcase its Revivent™ Myocardial Anchoring System at the European Heart Failure Congress (HFC) 2013, May 25-27 in Lisbon, Portugal. In clinical studies, the Revivent technology has demonstrated the ability to exceed a recently defined threshold for improving survival in HF patients. Data from a recent subgroup analysis of the National Institute of Health (NIH)-sponsored Surgical Treatment for Ischemic Heart Failure (STICH) study concluded that reducing the volume of the left ventricle (LV) to less than 60mL/m<sup>2</sup> provided a statistically significant improvement in survival for patients suffering from HF 1.

The landmark STICH trial sought to determine whether HF patients who had their LV surgically reduced (surgical ventricular reconstruction or SVR) concomitant with coronary artery bypass grafting (CABG), a procedure for diverting blood flow around blocked coronary arteries, lived longer than patients who had CABG alone. During a heart attack the portion of the LV muscle deprived of blood dies, creating a scar that does not contract along with the rest of the LV. These scars prevent the LV from efficiently pumping blood to the rest of the body. As the volume-overloaded LV becomes larger, HF develops and worsens, severely impairing quality of life and ultimately leading to death.

The subgroup analysis of the STICH trial confirmed improved survival for HF patients who undergo SVR plus CABG—when the LV end systolic volume index (LVESVI) is reduced to less than 70mL/m<sup>2</sup>, and a statistically significant improvement when lowered to less than 60mL/m<sup>2</sup>. Data from Phase I trials of the Revivent System across 26 patients showed an average reduction in LVESVI at six and 12 months to 57.3 and 57.4mL/m<sup>2</sup> respectively, well below the recognized threshold.

“The subgroup analysis of the STICH trial suggests that a threshold for left ventricular reduction that SVR techniques should target to provide a survival benefit may exist,” said Stefan Anker, M.D., Professor of Cardiology, Virchow Klinikum, Berlin, Germany, and president of the Heart Failure Association of the European Society of Cardiology. “When performed by well-trained physicians, conventional SVR can achieve the patient survival benefit threshold, but its invasive nature limits the heart failure population who can tolerate the procedure.” The Company’s presence at “HFC 2013” includes an oral abstract, a Hands-on Tutorial program and

participation in the “What’s New in Industry?” symposium. The oral abstract, “Prospective Study of the Revivent System for the Treatment of Ischemic Cardiomyopathy,” will be presented on Sunday, May 26, by John Teerlink, MD, Director of the Heart Failure Program at San Francisco Veteran’s Administration Hospital in San Francisco, Calif., USA. During the Hands-on Tutorial, physicians will have an in-depth opportunity to simulate a LIVE procedure and learn how the Revivent system can be implanted without performing cardiopulmonary bypass or making surgical incisions on the heart.

“Our presence at the Heart Failure Congress in Lisbon will allow us to inform the leading heart failure specialists across the European Union about the benefits of the Revivent System and how it impacts patient survival,” said David Schickling, vice president of sales and marketing at BioVentrix. “The STICH trial subgroup analysis validates our concept that reducing and reshaping the ventricle to its more native geometry can attack the cause of heart failure progression.” About the Revivent™ System: Attacking the Cause of Heart Failure The Revivent™ Myocardial Anchoring System addresses the safety concerns of physicians about subjecting patients to invasive surgical interventions on the heart’s left ventricle. The Revivent system, placed using the LIVE™ procedure, can be performed as a separate standalone procedure, concurrent with other procedures (e.g., CABG or transcatheter mitral valve procedures) or during other occasions when a sternotomy is already employed. Neither a myocardial incision nor cardiopulmonary bypass is required. Additionally, the Revivent system is deployed using a straightforward, epicardial approach that can be completed in about one hour. The Revivent System received CE-marking in November 2012 and is currently available to physicians in the European Union.

About LIVE™: The World’s Only Reshaping, Restorative Left Ventricle Therapy Less Invasive Ventricular Enhancement™ (LIVE™) therapy is an innovative off-pump (i.e., beating heart) procedure that helps restore the left ventricle’s intrinsic functional efficiency, rather than relying on a surrogate pumping device or other invasive treatment. The only therapy currently designed to restore optimal left ventricle size and function, LIVE provides physician teams with a gentler surgical option that enables them to more confidently treat heart failure patients who may not tolerate left ventricle incisions. LIVE bridges a need in available heart failure treatments, offering the potential for more consistent and favorable surgical outcomes, while giving heart failure patients and their families renewed hope for a more productive life.

About BioVentrix BioVentrix, a privately held medical technology company headquartered in San Ramon, Calif., is focused on developing and commercializing minimally invasive as well as nonsurgical therapies for treating heart failure (HF).

NOTE: The Revivent™ Myocardial Anchoring System™ requires regulatory approval and is not yet commercially available in the United States.

1 Michler R et al. Insights from the STICH trial: Change in left ventricular size after coronary artery bypass grafting with and without surgical ventricular reconstruction. J of Thoracic and Cardiovascular Surgery. 29 October 2012

## **BioVentrix to Exhibit Revivent™ System, which Surpasses Survival Benefit**

Published on Medical Design Technology (<http://www.mdtmag.com>)

---

(10.1016/j.jtcvs.2012.09.007).

**Source URL (retrieved on 04/01/2015 - 1:17pm):**

[http://www.mdtmag.com/news/2013/05/bioventrix-exhibit-revivent%E2%84%A2-system-which-surpasses-survival-benefit-threshold-heart-failure-treatment-european-heart-failure-congress?qt-video\\_of\\_the\\_day=0](http://www.mdtmag.com/news/2013/05/bioventrix-exhibit-revivent%E2%84%A2-system-which-surpasses-survival-benefit-threshold-heart-failure-treatment-european-heart-failure-congress?qt-video_of_the_day=0)