Updated ‘STICH’ Study Concludes That Surgical Ventricular Reconstruction (SVR) in Conjunction with CABG Decreased Mortality by 64% in Heart Failure Patients Compared with CABG Procedure Alone at Four-Year Follow-up

The Associated Press

SAN RAMON, Calif.--(BUSINESS WIRE)--Jan 28, 2013--BioVentrix, an emerging medical device company, announced today that updated clinical data from the ‘STICH’ trial now in press and soon to be published in the Journal of Thoracic and Cardiovascular Surgery concludes: “In patients undergoing coronary artery bypass grafting (CABG) plus Surgical Ventricular Reconstruction (SVR), a survival benefit was realized compared with bypass alone in patients where the LV (Left Ventricle) volume was reduced below 70 mL/m 2.” ‘STICH’ refers to ‘Surgical Treatment for Ischemic Heart Failure.’ Funding for the STICH study was provided by grants from the National Heart, Lung, and Blood Institute (NHLBI).

More importantly, in patients treated with CABG and SVR, those who achieved a postoperative LVESVI (Left Ventricular End-Systolic Volume Index) of less than 60 mL/m 2 showed a 64% reduction in mortality (9.8% vs. 27%) at four years as compared with those whose LVESVI was 60 ml/m 2 or greater. BioVentrix has previously reported a superior LV volume reduction mean of 56 mL/m 2 in its First-in-Man study. Consequently, the independent STICH study’s updated results underscore the potentially critical clinical impact of BioVentrix’s Revivent™ Myocardial Anchoring System, which makes possible Less Invasive Ventricular Enhancement™ (LIVE™), an SVR procedure that restores the Left Ventricle from damage done by a heart attack to a more optimal volume and conical shape, thereby enhancing performance of the heart’s non-damaged myocardium and improving quality of life.

"There has been considerable debate over whether SVR in conjunction with CABG decreases mortality or hospitalization rates compared with CABG alone,” said Vasco Gama, M.D., Cardiovascular Interventional Unit, Department of Cardiology, Gaia Hospital Center, Vila Nova de Gaia, Portugal. “The STICH data analysis demonstrates that there are patient populations who truly benefit from Surgical Ventricular Reconstruction. For example, survival rates show improvement in ischemic cardiomyopathy patients with post-op LVESVI of less than or equal to 70 mL/m 2. As a cardiologist seeking less-invasive therapy, I find the Revivent technology to be well-suited for such patients.Long-term follow-up data show that Revivent achieves LV scar exclusion, significant LV volume reduction, and symptomatic improvement in patients. Equally important, these impressive clinical outcomes are achieved without cardiopulmonary bypass or ventriculotomy." “The Revivent system used during LIVE procedures is enabling cardiac surgery teams not only to ensure optimal clinical outcomes and enhance quality of life for heart failure

patients but also to minimize risk compared to the previous gold standard of conventional left ventricle reconstruction surgery," added Kenneth Miller, president and chief executive officer of BioVentrix. "Further, our forthcoming Transcatheter technology will make the LIVE procedure available to even a more-frail and elderly population who cannot tolerate conventional open-heart surgery." About Revivent™: A Less-Invasive Intervention for Heart Failure Patients The Revivent™ Myocardial Anchoring System addresses the safety concerns of physicians about subjecting patients to invasive surgical interventions on the heart's left ventricle. Made possible by the Revivent system, the LIVE™ procedure can be performed as a separate stand-alone procedure, concurrent with other procedures (e.g., CABG) 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.

About LIVE™: The World's Only Reshaping, Restorative Left Ventricle Therapy Less Invasive Ventricular Enhancement™ (LIVE™) therapy is an innovative, new 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 fills the gap 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 is not approved for sale in the United States.

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