BioVentrix receives CE mark for its Revivent® Myocardial Anchoring System

The Associated Press

SAN RAMON, Calif.--(BUSINESS WIRE)--Dec 3, 2012--BioVentrix, an emerging medical device company, announced today that it has received CE marking for its Revivent™ Myocardial Anchoring System, which makes possible Less Invasive Ventricular Enhancement™ (LIVE™), a 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.

Prior to Revivent™, reshaping of the left ventricle required an invasive procedure known as surgical ventricular restoration (SVR), which required stopping the beating heart and supporting it with cardiopulmonary bypass, while significant incisions into the heart muscle are made to excise the scarred, non-functioning (ischemic) 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 less invasive LIVE™ procedure using the Revivent™ system is performed without the need of cardiopulmonary bypass or making incisions into the heart.

"Heart failure in Europe is more common than most cancers," said Louis Labrousse, M.D., professor of Cardiovascular Surgery at Hopital Haut-Lévêque, Bordeaux-Pessac, France. "Prior to the availability of Revivent, open-heart surgery could only be applied sparingly among this very fragile patient population due to its invasiveness. There are some 14 million people in Europe who currently suffer from heart failure. Unfortunately, this number is expected to more than double by 2020. Thus, regulatory approval of Revivent is significant news for ischemic heart failure patients throughout Europe." "Because of Revivent, the LIVE procedure can be performed without cardiopulmonary bypass: therefore the heart is beating and stable, and there is no major surgical incision in the myocardium," added Andrews S. Wechsler, M.D., professor of Cardiothoracic Surgery, Drexel University College of Medicine, Philadelphia. "Intraoperative monitoring has documented the excellent hemodynamics present at the end of the LIVE procedure without vasoactive support. No doubt, regulatory approval of Revivent will have a significant impact on the treatment of heart failure patients in Europe going forward." "Our innovative Revivent system used during LIVE procedures will empower 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," said , president and chief executive officer of BioVentrix. "While we are extremely pleased with the regulatory approval of Revivent in Europe, we are also looking forward to our next-generation Revivent technology — transcatheter ventricular restoration (TCVR)," added Miller. "Given the successful clinical outcomes we have achieved with Revivent, we have

fast-forwarded development of our next-gen, endovascular technology designed to achieve the same results as the LIVE procedure, but with a sternal-sparing technique. This closed-chest, beating heart, transcatheter therapy is expected to be a new paradigm for treating heart failure patients, holding great promise for those who have suffered a heart attack but are just too sick to tolerate invasive 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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