CardioKinetix Announces Positive Three-Year Clinical Data for First-of-Its-Kind Minimally Invasive Treatment for Heart Failure

The Associated Press

MUNICH & MENLO PARK, Calif.--(BUSINESS WIRE)--Aug 27, 2012--CardioKinetix Inc., a medical device company pioneering a catheter-based treatment for heart failure, today announced clinical results showing meaningful and sustained low clinical events for patients with ischemic heart failure three years following Percutaneous Ventricular Restoration (PVR) therapy with the first-of-its-kind catheter-based Parachute™ Ventricular Partitioning Device.

Findings were presented today in Munich during the State of the Art – Novel Concepts in Heart Failure Treatments session at the 2012 European Society of Cardiology Conference by Marco Costa, M.D., Ph.D., director of the Interventional Cardiovascular Center and the Research and Innovation Center at the Harrington Heart & Vascular Institute, University Hospitals Case Medical Center, and professor of medicine, Case Western Reserve University in Cleveland, Ohio.

Data from thirty-one patients treated in the U.S. and Europe with the Parachute system demonstrate that the New York Heart Association (NYHA) class improvement observed at one and two years was maintained at three years post treatment (average NYHA class of 2.6 at baseline vs. 1.8 at three years, $p<0.0001$). The rate of hospitalization due to worsening heart failure was 29.7 percent at two years and 33.2 percent at three years, and the low rate of cardiac death of 6.5 percent at two years remained unchanged at three years, suggesting that percutaneous ventricle restoration with the Parachute system results in a plateau of the progression of heart failure in these patients. These outcomes compare favorably with current medical therapy in a similar high-risk patient population.

“These results are compelling. The sustained improvements in functional capacity and plateauing effect seen in outcomes three years after treatment with the Parachute device are particularly encouraging, showing that we may be able to slow the progression of heart failure – a very exciting prospect,” said William T. Abraham, M.D., director of the Division of Cardiovascular Medicine and professor of internal medicine, physiology and cell biology at The Ohio State University Medical Center.

“We were already very excited about the two-year clinical data presented at the EuroPCR conference earlier this year. The unprecedented three-year results observed in this high-risk population treated with Parachute reinforces our initial enthusiasm and fuels our motivation to start the pivotal large randomized trial later this year,” said Dr. Costa. “In the two first-in-man studies, the Parachute device demonstrated its safety and sustained improvements in symptoms, heart function, and clinical outcomes over three years, pointing to a potential historical turning

point in the treatment for post-MI heart failure patients." "This innovative device could address a significant unmet need in ischemic heart failure, with the potential to improve the lives of thousands patients with this debilitating condition," said Maria Sainz, president and CEO of CardioKinetix. "We are focused on completing our real-world European post-market surveillance trial and initiating our U.S. pivotal trial to pursue our plans to bring this therapy to patients suffering from heart failure globally." Many heart attack survivors experience enlargement of the heart, causing a decrease in cardiac output that results in heart failure symptoms such as fatigue and shortness of breath. The healthy portion of the heart not affected by the heart attack has to compensate for the loss in output and becomes overloaded over time. Current treatment options for patients whose hearts have enlarged are limited. The Parachute device offers the first minimally invasive catheter-based treatment to partition the damaged muscle, excluding the non-functioning, damaged heart muscle from the healthy, functional segment to decrease the overall volume of the left ventricle chamber and restore its optimal geometry and function.

About Heart Failure Heart failure is a common, debilitating, and potentially deadly condition in which the heart is unable to supply sufficient blood flow to meet the needs of the body. Symptoms of heart failure negatively impact quality of life and include shortness of breath, persistent coughing or wheezing, buildup of excess fluid in body tissues (edema), fatigue, lack of appetite or nausea, impaired thinking, and increased heart rate. More than 20 million people around the world are affected, with approximately six million in the United States, where it is responsible for 1.1 million hospitalizations annually. 1 About the Parachute™ Ventricular Partitioning Device The first-of-its-kind Parachute Ventricular Partitioning Device is a minimally invasive treatment for patients with heart failure caused by damage to the heart muscle following a heart attack. Clinical data demonstrates improved overall cardiac function and quality of life for patients treated with the Parachute device.

Through a small catheter inserted in the femoral artery, the Parachute implant is deployed in the left ventricle to partition the damaged muscle, excluding the non-functional heart segment from the healthy, functional segment to decrease the overall volume of the left ventricle and restore its geometry and function. This minimally invasive procedure is performed in the catheterization laboratory under conscious sedation.

The Parachute Ventricular Partitioning Device received CE Mark in 2011. In the U.S., the Parachute system is an investigational device limited by federal law to investigational use only and is not available for sale.

About CardioKinetix Inc. CardioKinetix, based in Menlo Park, Calif., is pioneering the catheter-based Parachute™ Ventricular Partitioning Device for heart failure. Privately held, the company is backed by SV Life Sciences, New Leaf Venture Partners, U.S. Venture Partners, Panorama Capital, and H&Q Healthcare Investors. For more information please visit www.cardiokinetix.com.

1 Heart disease and stroke statistics – 2012 update: a report from the American Heart Association. Circulation 2012; 125: e2-e220.

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