CardioKinetix Announces Data From Latest European Study of Heart Failure Patients With First-of-Its-Kind Percutaneous Treatment

The Associated Press

MENLO PARK, Calif.--(BUSINESS WIRE)--Oct 24, 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 following Percutaneous Ventricular Restoration (PVR) therapy with the first-of-its-kind catheter-based Parachute™ Ventricular Partitioning Device.

Data was shown at two presentations today in Miami at the annual Transcatheter Cardiovascular Therapeutics (TCT) 2012 conference.

Dr. Martyn Thomas, M.D., chairman of Cardiology at St. Thomas' Hospital in London, England, presented six-month data from 32 patients treated in a European confirmatory trial. These data demonstrate a New York Heart Association (NYHA) class improvement of nearly half a class from a baseline of 2.5 to 2.1 ($p < 0.01$). The rate of hospitalization due to worsening heart failure was 12.5 percent at six months, with no incidence of stroke or death, confirming the results from the feasibility trials.

Dr. Marco Costa, M.D., Ph.D., professor of medicine, Case Western Reserve University in Cleveland, Ohio, presented three-year data from 31 patients treated in feasibility trials from the U.S and Europe. Results demonstrate a rate of hospitalization due to worsening heart failure of 29.7 percent at two years and 33.2 percent at three years for patients treated with the Parachute system, with the low rate of cardiac death of 6.5 percent at two years remaining unchanged at three years. These results suggest that percutaneous ventricle restoration with the Parachute system results in a plateau of the progression of heart failure in these patients. These outcomes compare very favorably with current medical therapy in a similar high-risk patient population.

"With data now at three years, the long-term effect of the Parachute procedure remains highly promising for percutaneous treatment of heart failure patients. Particularly encouraging is the plateauing effect still maintained three years after treatment, which points to a potential slowing in the progression of heart failure," said Dr. Thomas. "The durability of these results are demonstrated by the six-month results from the latest cohort of data, which are nearly the same as the feasibility results. Since the most recent cases were all done by operators without prior Parachute experience, the adoptability of this technology is very promising." "We continue to be very excited about the Parachute device and the promise it holds for addressing a significant unmet need for patients with debilitating ischemic heart failure," said Maria Sainz, president and CEO of CardioKinetix. "In the next few

months we look forward to initiating our U.S. pivotal trial, PARACHUTE IV, and beginning our European launch, two major milestones for our company." 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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