Results Presented at EuroPCR Demonstrate Meaningful and Sustained Improvement in Clinical Outcomes, Suggesting Breakthrough Treatment for Heart Failure Patients

The Associated Press

PARIS & MENLO PARK, Calif.--(BUSINESS WIRE)--May 18, 2012-- CardioKinetix Inc., a medical device company pioneering a catheter-based treatment for heart failure, today announced two-year clinical results for the first-of-its-kind catheter-based Parachute(TM) Ventricular Partitioning Device, a Percutaneous Ventricular Restoration (PVR) therapy for patients with ischemic heart failure. Results were presented today during a Trials, Registries and Late Breaking Science Hot Line session at the 2012 EuroPCR Conference in Paris by Marco Costa, M.D., Ph.D., director of the Interventional Cardiovascular Center and the Research and Innovation Center at the Harrington Heart and Vascular Institute, University Hospitals Case Medical Center, Case Western Reserve University in Cleveland, Ohio.

Clinical data from the two first-in-human studies of the Parachute system presented today show meaningful and sustained low clinical events for patients with ischemic heart failure two years following treatment with the device.

Results from 31 treated U.S and European patients demonstrate a near-full New York Heart Association (NYHA) class improvement at two years compared to baseline (2.6 vs. 1.9, $p<0.01$). In addition, reduction in left ventricular volume was maintained out to two years ($p<0.001$). Furthermore, the procedure stabilized the remodeling process as demonstrated by no statistical change in post-procedure functional volume over a two-year period ($p=0.74$). The combined rate of all-cause death and hospitalization due to worsening heart failure was 16.1 percent at one year and 32.3 percent at two years. The rate of cardiac death was 6.5 percent at two years. These outcomes compare favorably with current medical therapy in a similar high-risk patient population.

"Heart failure is such a morbid condition and, in spite of our best efforts, we have so little to offer to our patients. Today we shared unprecedented news for cardiologists and heart failure patients. It is difficult to contain our enthusiasm because the procedure is relatively simple and the outcomes are surprisingly remarkable for such a high-risk population," said Dr. Costa. "The sustained and concordant improvements in symptoms, heart function, and clinical outcomes are compelling, with a very acceptable safety profile. If these results are confirmed in the upcoming large randomized trial, the Parachute implant will revolutionize the treatment of patients with ischemic dilated cardiomyopathy, reducing debilitating symptoms and allowing patients with heart failure to live with dignity again." "We are extremely pleased with the two-year clinical results from the Parachute implant. This data supports the design of our randomized pivotal trial, in which we anticipate a

potential reduction of death and hospitalization due to worsening heart failure on the order of 30 to 50 percent for patients treated with the Parachute system compared to optimal medical therapy," 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. "This innovative device has the potential to bring together two cardiology disciplines - heart failure and interventional cardiology - to address a significant unmet need in heart failure." "The presentation of this long-term clinical data is an exciting milestone for CardioKinetix," said Maria Sainz, president and CEO of CardioKinetix. "We look forward to gathering additional evidence of the clinical benefits of the Parachute from our European trials as we prepare to start our pivotal trial of the device, which we believe holds the potential to improve the lives of tens of thousands of patients around the world." After a heart attack, many patients experience enlargement of the left ventricle 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 heart has enlarged are limited. The Parachute device offers the first minimally invasive catheter-based treatment 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.

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(TM) 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(TM) 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.

Photos/Multimedia Gallery Available: http://www.businesswire.com/cgi-bin/mmg.cgi?eid=50282872&lang=en CONTACT: CardioKinetix Barry Templin, 650-364-7016 barry@cardiokinetix.com KEYWORD: UNITED STATES EUROPE NORTH AMERICA CALIFORNIA FRANCE INDUSTRY KEYWORD: HEALTH CARDIOLOGY CLINICAL TRIALS HOSPITALS MEDICAL DEVICES SOURCE: CardioKinetix Inc.

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