PARACHUTE III Clinical Trial Will Evaluate Benefits of Therapy in Real-World Setting

The Associated Press

MENLO PARK, Calif.--(BUSINESS WIRE)--Jun 7, 2012-- CardioKinetix Inc., a medical device company pioneering a catheter-based treatment for heart failure, announced today that it has begun enrollment in PARACHUTE III, a post-market safety surveillance trial, in Germany with the CE Marked Parachute(TM) Ventricular Partitioning Device.

After a heart attack, many heart failure patients experience enlargement of their left ventricle causing a decrease in cardiac output resulting in heart failure symptoms such as shortness of breath. Treatment options for patients whose ventricle 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.

The first implants with CE Marked Parachute devices were done in Heidelberg, Germany by Stefan Hardt, M.D., Department of Cardiology, Heidelberg University Clinic as part of the PARACHUTE III trial, which is designed to evaluate the long-term safety of the Parachuteimplant in a real-world setting in up to 100 patients with ischemic heart failure at up to 20 centers in Europe. Professor Hardt reported that all patients were treated successfully and discharged without procedure-related complications. A successful case was also performed by Heyder Omran, M.D., Ph.D., Department of Cardiology and internal Medicine, St. Marien-Hospital Abt. Innere Medizin in Bonn, Germany.

"The Parachuteimplant system represents an important advancement in treatment options for patients with ischemic heart failure," said Dr.

Martyn Thomas, M.D., chairman of Cardiology at St. Thomas Hospital in London, England, and the principle investigator for the PARACHUTE III study. "These first procedures in the PARACHUTE III trial represent the beginning of the largest clinical data evaluation for this new therapy to date. I am optimistic that the patients treated with the Parachute implant will experience positive results similar to those in prior trials of the device most recently reported during the 2012 EuroPCR meeting." CardioKinetix plans to continue expanding its post-marketing trial effort in Europe by adding hospitals in the UK, Spain, Italy, Belgium, Germany, and the Netherlands in coming months. The PARACHUTE III clinical trial will enable physicians in the European Union to increase their experience with the technology while continuing to develop the therapy.

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.i 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 the PARACHUTE III Trial PARACHUTE III is a dual-arm (Parachute vs. optimal medical therapy), open-label, multi-center trial designed to evaluate the Parachute implant in a real-world setting. The trial will enroll up to 100 patients with ischemic heart failure at up to 20 centers in Europe.

The primary endpoint of the trial is procedural- and device-related Major Adverse Cardiac Events (MACE) through 60 months. Other key endpoints include hemodynamic measures by echocardiography (ECHO) and imaging measures by computed tomography (CT).

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.

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

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