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MiCardia® Announces First Patients Implanted in D.Y.A.N.A. Clinical Study

IRVINE, Calif.--(BUSINESS WIRE)--MiCardia® (MiCardia Corporation, Irvine, California) announced the successful implant of its device in two patients who received MiCardia's new Dynaplasty® mitral valve repair technology. The surgery was performed at the Department of Cardiovascular Surgery, University Hospital, Kiel, Germany, the first week of December. This marks the commencement of the Company's European **Dynamic Annuloplasty Activation (DYANA)** Study designed to provide data for CE Mark of the Company's groundbreaking Dynaplasty® Technology.

Professor Jochen Cremer M.D. Ph.D., who leads the cardiac surgery team at the University Hospital noted, "This is a new generation of dynamic repair device. It implanted easily using a conventional approach and the patients are doing well. We are excited to be participating in the **DYANA** Study and believe Dynaplasty® technology will address a major weakness of current devices, namely their inability to deal with changes in valve shape and function after the initial repair procedure."

Commenting on the initiation of the clinical phase of the study, **MiCardia®** Chief Executive Officer Paul Molloy said, "This is a major milestone for **MiCardia®**. We expect to complete enrollment and submit six month follow up data from the **DYANA** Study in 2009 as a prelude to European commercialization of the world's first dynamically activated heart valve repair system."

MiCardia® received a 510(k) clearance on the static version of its Dynaplasty® System in September 2008 and implants will commence shortly at several prestigious centers in the United States. The Company plans to submit US implant data as part of its European CE Mark submission and in turn capture critical clinical data from its European **DYANA** Study to support regulatory submissions and commercialization of its systems in the USA subsequently.

MiCardia® is developing Dynaplasty® technology for the treatment of structural heart disease, focusing initially on mitral and tricuspid valve disorders and as a method of interrupting a major element in the onset and progression of Congestive Heart Failure (CHF).

MiCardia® is a privately held company, founded in 2004 and is developing a completely unique treatment technology that will allow adjustment of cardiac anatomy both intra-operatively and post-operatively. Surgical, percutaneous and entirely non-invasive activation platforms are in advanced development.

The MiCardia Dynamic Annuloplasty System is not currently available in the USA. Non-US clinical evaluation is in progress. Not available for sale. MiCardia, Dynaplasty and Dynamic Annuloplasty System are registered trademarks of MiCardia Corporation. All rights reserved.

Contacts

MiCardia®
Mr. Paul Molloy, Chief Executive Officer
pmolloy@MiCardia.com
+1-949-951-4888, ext 36

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