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MiCardia® Announces Completion of Enrollment in "DYANA" European CE Study

MiCardia® (*MiCardia® Corporation, Irvine, California*) today announced the completion of enrollment in its European "DYANA" (**Dy**namic **An**nuloplasty **A**ctivation) study, designed to support submission for CE mark of the firm's Dynaplasty® technology in Europe.

Thirty patients were implanted with MiCardia's patented shape memory Dynaplasty® mitral repair system, twenty-five in Germany at Homburg; Kiel; Leipzig and Stuttgart with five at William Beaumont Hospital in the US, the latter implanting a non-activation version of the device. Of the European implants, one quarter were successfully activated for correction of residual mitral regurgitation post-operatively. The company will submit six month follow up data early in 2010 as part of its CE Mark submission. First clinical indicators of device success are all positive. The enrolling hospitals and several new sites are set to continue implantation going forward, supporting the Company's strategy to expand its base of clinical validation of Dynaplasty®.

Dr. Frank Shannon, who completed the US cohort of the study commented, "MiCardia's unique Dynaplasty® provides a precise geometrical adjustment of the annulus shape without the reduction in effective orifice area that conventional restrictive annuloplasty dictates. We have seen a high demand for this functionality in the immediate post-operative phase which bodes well for the usefulness of the technology for these patients who have so few good choices today".

Remarking on the enrollment milestone, MiCardia's Chief Executive Officer, Paul Molloy said "MiCardia® is grateful to the vision and hard work of the physicians involved in our DYANA study. To see a 25% rate of acute activation in a relatively modest sized cohort of European patients indicates the potential for MiCardia 's Dynaplasty® technology."

The Company plans to apply for CE Mark of its first Dynaplasty® product and then add "late stage" activation capability to its devices. This will completely transform the approach to treating recurrent valve regurgitation by making it possible to adjust mitral and tricuspid valve leaflets long after the initial implant with no repeat surgery required. This will be done as an outpatient procedure, on a beating heart. No such option exists for these patients today.

Mitral valve regurgitation is closely associated with the risk of heart failure. There are about fifteen million people in heart failure in Europe and the US, of which half suffer from mitral valve regurgitation.

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.

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