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## **MiCardia Corporation Receives CE Mark Clearance to Market enCor™ Dynamic Mitral Valve Repair System in the European Union**

IRVINE, Calif.--([BUSINESS WIRE](#))--**MiCardia Corporation** announced today that it has received the CE Mark to begin marketing the Company's **enCor™ Mitral Valve Repair System** in the European Union.

**“We thank the clinical investigators who participated in the Company’s DYANA study that provided the clinical data that validate enCor’s ability to reduce mitral valve regurgitation.”**

The enCor device offers unique benefits to patients and physicians during mitral valve repair surgery, a procedure to address mitral regurgitation, performed annually on thousands of patients worldwide. The enCor device provides a physician a device that can dynamically adjust the mitral valve annulus to correct any residual mitral valve regurgitation intra-operatively, in real-time on a beating heart (off-bypass-pump). In the European Union approximately 20,000 mitral valve repair procedures are performed annually.

“Obtaining the CE Mark approval for MiCardia’s first product is a significant milestone towards developing the Company’s marketing infrastructure, which will be initially focused in the European Union. The enCor Mitral Valve Repair System has been presented and widely accepted in several EU medical meetings this past fall,” said Don Rohrbaugh, the company’s Chief Executive Officer.

Samuel Shaolian, the Company’s co-founder and Chief Technology Officer, said, “We thank the clinical investigators who participated in the Company’s DYANA study that provided the clinical data that validate enCor’s ability to reduce mitral valve regurgitation.” He added, “Our next generation, enCorSQ™, will enable clinicians to dynamically adjust the device in a minimally invasive manner, to correct recurrent mitral valve regurgitation due to the progression of the underlying cardiovascular disease, weeks or months post implantation. Many experts believe the enCor will be a breakthrough in the treatment of mitral valve disease.”

### **About Mitral Regurgitation**

Mitral regurgitation (MR), the most common type of heart valve insufficiency, occurs when the heart’s mitral valve does not close properly. Both the American Heart Association and the American College of Cardiology recommend open-heart surgery to repair or replace the mitral valve for patients who suffer from moderate-to-severe

(Grade 3+) and severe (Grade 4+) MR; open heart surgery is not recommended for patients with Grade 1 to 2+ MR. An estimated four million people in the United States have significant (>2+) MR, with an annual incidence of 250,000 newly diagnosed patients.

## **About MiCardia and enCor**

MiCardia is a privately held medical device company currently preparing for the commercialization of its first series of products, *enCor™*, in the European Union. *enCor* is a unique device that is surgically implanted to treat mitral valve regurgitation. *enCor* utilizes the company's patented technology, *Dynaplasty™*, to provide a 'second chance' for the surgeon to adjust the ring dynamically to correct residual regurgitation.

The company is also developing a unique, second generation product, the *enCorSQ*. The *enCorSQ* can be activated to reshape the mitral valve annulus to resolve regurgitation, minimally invasively, weeks, months or years later, without the need for the risk and cost of redo surgery. A clinical study on the *enCorSQ* is planned for early 2011.

Currently in development is the Company's *enCorTC*, which will provide the capability to implant the *Dynaplasty* Technology interventionally. The *enCorTC* will be delivered via a catheter delivery and anchoring system, providing a totally *non-surgical*, lower risk method to treat mitral valve regurgitation.

For further information, please visit [www.micardia.com](http://www.micardia.com).

*The MiCardia enCor Dynamic Annuloplasty System is not currently available for sale in the USA. MiCardia, Dynaplasty, enCor and enCor Mitral Valve Repair System are registered trademarks of MiCardia Corporation. All rights reserved.*

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