

FIRST PATIENTS TREATED IN ITALY WITH THE PERCUTANEOUS MITRACLIP® SYSTEM

Use of the MitraClip® System Expands in the European Union

MENLO PARK, Calif. October 21, 2008 Evalve, Inc., the leader in the development of devices for the percutaneous repair of cardiac valves, announced today that the first two patients in Italy have been treated with the MitraClip® system at Ferrarotto Hospital in Catania, Italy. The MitraClip® system is the first commercially available medical device which provides a non-surgical mitral valve repair option for patients suffering from the effects of mitral regurgitation (MR).

MR is the second most common type of heart valve insufficiency in Europe, and the most common in the United States, affecting millions of people worldwide. Both in Europe and the United States, the vast majority of patients are untreated, which leaves their hearts affected by the chronic volume overload caused by MR, requiring the heart to work harder, and ultimately leading to heart failure.

The first patients in Italy were treated by the team led by Corrado Tamburino, M.D., Gian Paolo Ussia, M.D., Salvatore Scandura, M.D., and Sarah Mangiafico, M.D. at the University of Catania in Sicily, Italy.

“The MitraClip® is a new option for high risk patients as well as patients who are not willing to undergo the standard surgical treatment for mitral insufficiency,” said Prof. Corrado Tamburino, chair of cardiology, cardiology department, cardiac catheterization and interventional cardiology, Ferrarotto Hospital, University of Catania, Sicily. “I hope that this technique will be broadly adopted to treat suitable patients requiring a correction of mitral regurgitation.”

“The procedural efficacy of the MitraClip® system is enhanced by the ability to reposition the clip to achieve an optimum result”, said Gian Paolo Ussia, M.D., director of the interventional structural and congenital heart disease program, Ferrarotto Hospital, University of Catania, Sicily. “I believe this technique can be safely proposed to patients with severe mitral regurgitation with an expected benefit in terms of functional class improvement.”

Evalve received CE Mark approval for the MitraClip® system this year, and has worked with hospitals across Europe to establish training programs in support of the European roll out. Commercial sales started in September. Multiple European centers are in the process of scheduling treatments of the first groups of patients, in addition to the University Heart Center in Hamburg, Germany which announced completion of its first case earlier in October. These additional sites include Hospital San Raffaele, Milan, Italy; and Cardiovascular Center Frankfurt, Frankfurt, Germany.

“The first procedures in Italy mark a notable milestone for people worldwide suffering from MR”, said Ferolyn Powell, president and chief executive office of Evalve. “Until now, surgery was the only available treatment option for repairing the mitral valve in MR patients. The MitraClip® system offers suitable patients a new alternative that allows them to avoid the associated risks and trauma of surgery.”

About the MitraClip® Procedure

Percutaneous mitral repair with Evalve's MitraClip® device is performed by physicians in the catheterization laboratory. The heart beats normally during the procedure, and therefore does not require a heart-lung bypass machine. In addition to improving blood flow through the heart, the procedure may also relieve symptoms such as fatigue and shortness of breath that often affect patients with significant MR. After treatment, patients generally recover quickly. The MitraClip® device may improve quality of life and may help MR patients avoid or delay surgery, having preserved surgical options (valve repair or replacement) should surgery become necessary.

About Evalve, Inc.

Founded in 1999, Evalve, Inc. -headquartered in Menlo Park, California- has developed a proprietary system which enables percutaneous repair of cardiac valves. The company's initial products are intended to reduce the risks, trauma and costs associated with current open, arrested heart surgical options. For more information about Evalve, Inc., and for an animated explanation of the Percutaneous Mitral Repair procedure using the MitraClip® device, visit www.evalveinc.com. Evalve is the first portfolio company from the medical device company incubator, The Foundry (www.thefoundry.com).

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