



FOR IMMEDIATE RELEASE

Mitralign Completes Enrollment in EU Study for its Novel Catheter-based Valve Repair Device

Company to seek CE Mark for new first-line percutaneous treatment of functional mitral regurgitation

TEWKSBURY, Mass. – April 8, 2014 – [Mitralign Inc.](#), a cardiac device company, announced today it has completed enrollment in a study in Europe investigating its lead device, the Mitralign System, in patients with functional mitral regurgitation (FMR). Pending successful outcomes from the study, the company will seek CE Mark approval in the European Union (EU) as a first step toward commercializing the Mitralign System. Receiving the CE Mark demonstrates that a product has been assessed by the European Commission for Enterprise and Industry and meets EU safety, health and environmental protection requirements.

“This is an important milestone for our company and brings our Mitralign System that much closer to patients who suffer this severe heart disease,” said Rick Geoffrion, chief executive officer of Mitralign. “We have completed the enrollment of 61 FMR patients in Europe, and we are in the process of collecting the necessary follow-up data for submission to our notified body in Europe for CE Mark approval. In the meantime, we will continue to enroll patients within our active clinical studies in order to accrue additional data for the medical community. We expect to report results from this trial before the end of 2014.”

FMR is a condition brought on by a single or series of ischemic events, such as a heart attack or by the onset of cardiomyopathy. Patients with FMR often see a progressive enlargement of the heart, stretching open the mitral valve to allow the backflow of blood within the heart, thereby exacerbating the deterioration of heart function.

The [Mitralign System](#) utilizes a system of wires and catheters to implant at least one pair of polyester anchors within the mitral annulus, a ring of tissue surrounding the mitral valve. The anchors are then cinched together, reducing the circumference of the mitral valve towards its normal size with a goal to improve heart function and assist in the alleviation of heart failure symptoms.

“Patients with FMR are very sick and often experience a dilation of the heart and the deterioration of heart function, despite optimal medical therapy,” said Georg Nickenig, M.D., Mitralign’s lead investigator and professor at the Universitätsklinikum Bonn in Germany. “It is our hope that this novel device will provide a therapeutic option for these patients and improve their quality of life.”

About functional mitral regurgitation

Mitral valve regurgitation, or mitral insufficiency, is the most common form of valvular heart disease and is a condition in which the heart’s mitral valve does not close completely, causing blood to leak back into the left atrium. More than 2.5 million people in the U.S. suffer from moderate or severe functional mitral regurgitation (FMR), with more than 250,000 new patients diagnosed each year. In Europe, mitral regurgitation is the second most frequent valve disease requiring surgery, after the aortic valve. The long-term prognostic implications of FMR have demonstrated a significant increase in risk for heart failure or death, which is directly related to the severity of the regurgitation. Left unchecked, FMR can lead to heart enlargement, heart failure and further progression of the severity of mitral regurgitation.

About the Mitralign System

Mitralign is developing an innovative, catheter-based valve repair technology for first-line percutaneous treatment of functional mitral regurgitation (FMR). The novel Mitralign System emulates surgical annuloplasty, or the surgical repair of leaking mitral valves, as it delivers a series of surgical implants directly into the mitral annulus through a catheter. The implants are cinched together, thus reducing the size of the mitral valve annulus and the valve opening, relieving the symptoms of regurgitation while preserving future clinical options for patients.

About Mitralign Inc.

Mitralign Inc. is a venture-backed, medical device company located near Boston, Mass. The privately-held company is funded by top-tier venture capitalists. Mitralign has developed a breakthrough technology for the reduction of functional mitral regurgitation (FMR), a life-threatening cardiac condition. The company's unique system is a front-line therapy that provides a new solution for interventional cardiologists and their patients. For the millions of patients who have exhausted other therapeutic options, the Mitralign System is a lifeline for them. For more information, visit www.mitralign.com.

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