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Mitralign Shows Positive Mitral Data at PCR

Mitralign Percutaneous Annuloplasty System shows improved valve function at six month; company anticipates CE marking in mid-2015

PARIS, FRANCE and TEWKSBURY, MA – May 21, 2015 –Mitralign shared six month data on its' Mitralign Percutaneous Annuloplasty System (MPAS) for treatment of functional mitral regurgitation (FMR) at PCR in Paris, France today. The prospective, multi-center, single arm study met its safety endpoint at 30 days and its performance endpoint at six months. In the clinical study, the MPAS demonstrated a statistically significant reduction in left ventricular diameter, significant reduction of both the A-P and S-L annular dimensions and a significant improvement of the patient's walking distance. The Mitralign Percutaneous Annuloplasty System is not approved for sale or distribution; however it is anticipated to receive CE marking in 2015.

"The data show statistically significant progress at six months, specifically in ventricular remodeling which is one cause of patient symptoms," said Prof. Georg Nickenig of the University of Bonn. "These encouraging data further support the use of percutaneous valve repair to treat this challenging patient population."

In his presentation, "Evaluation of the Mitralign Percutaneous Annuloplasty System for the treatment of FMR 6 month results" Nickenig showed that the system demonstrated a significant reduction in the anterior-posterior, A-P, and septal-lateral, S-L, dimensions of the annulus. Enhanced ventricular function was demonstrated by significant improvement in left ventricular end diastolic diameter and left ventricular end diastolic and systolic volumes.

"It is noteworthy that the Mitralign system has demonstrated safety and performance in a very challenging FMR patient population," commented Rick Geoffrion, chief executive officer of Mitralign. "The patients were all on optimal medical therapy and had an average ejection fraction of 33%. Such data illustrate the value this system brings to those patients dealing with FMR."

Mitralign is the only company to provide interventional cardiologists with the tool they need to perform minimally invasive, transcatheter procedures for both functional mitral regurgitation and tricuspid regurgitation. In other EuroPCR presentations, Prof. Dr. med. J. Schofer of the Medicare Center and Department for Percutaneous Interventions of Structural Heart Disease, Albertinen Heart Center, Hamburg discussed his successful use of the MPAS to perform a direct transcatheter annuloplasty on special access patients with tricuspid regurgitation. The company aims to treat tricuspid regurgitation using the same innovative technology as used with FMR, but with a modified delivery system.

About Functional Mitral Regurgitation (FMR)

The mitral valve controls blood flow from the left atrium to the left ventricle of the heart, allowing blood to flow in one direction through the heart and into the body. Functional Mitral Regurgitation (FMR) is the most common valve disease and occurs when the left ventricle of the heart is enlarged, called positive remodeling, and stretches the valve opening. Because of this remodeling, the valve leaflets are not able to come together and close properly, allowing blood to flow, or regurgitate, backwards into the atrium. Consequences can include heart failure or serious rhythm problems called arrhythmias. An estimated 4 million people in Europe and 4 million people in the United States have significant mitral valve insufficiency, also known as mitral regurgitation, with an annual incidence of 250,000.[1] If left untreated, FMR overloads the heart and can lead to or accelerate heart failure.

About Tricuspid Regurgitation (TR) Tricuspid regurgitation occurs when the tricuspid valve fails to open and close properly, causing blood to flow backwards into the right atrium. If left untreated, TR can lead to heart enlargement and heart failure. In the U.S. alone, there are an estimated 1.6 million patients suffering from TR.[2] It is estimated that 50% of patients with mitral regurgitation have moderate to severe tricuspid regurgitation.[3] TR is currently undertreated by surgery. In the U.S. surgeons treat only 5,500 patients per year, most of them in conjunction with left heart surgeries. When treating the valves, surgeons choose repair 90% of the time versus replacement (10%).[4]

About Mitralign Inc.

Mitralign Inc. is the valve repair company with the only direct transcatheter annuloplasty system designed to treat both functional mitral regurgitation and functional tricuspid regurgitation. The company is a venture-backed, medical innovation company located near Boston, Massachusetts, USA. For more information, visit www.mitralign.com.

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