



FOR IMMEDIATE RELEASE

Mitralign To Update On Mitral and Tricuspid Repair Systems at EuroPCR 2015

Mitralign Percutaneous Annuloplasty System for treating functional mitral regurgitation seeks CE mark approval in 2015

TEWKSBURY, MA – May 14, 2015 –Mitralign is reinforcing its position as the only company to provide a direct percutaneous annuloplasty system designed to treat both functional mitral regurgitation (FMR) and tricuspid regurgitation (TR). At EuroPCR the week of May 17 in Paris, the company will present updates on its mitral and tricuspid valve repair systems including a presentation of six month data on its Mitral system. The Mitralign Percutaneous Annuloplasty System (MPAS) is not approved for sale or distribution; however it is currently being evaluated in clinical trials for a CE mark indication. The MPAS for tricuspid regurgitation is not approved for sale or distribution, but is anticipated to begin clinical investigation in 2015.

“Safety and performance data for the Mitralign Percutaneous Annuloplasty System are very compelling and we are looking forward to CE marking this year,” said Rick Geoffrion, chief executive officer of Mitralign. “Our data show statistically significant improvements at six months including ventricular remodeling which has been stated as a goal for valve repair systems as it leads to improved patient symptoms.”

Updates on Mitralign’s percutaneous programs will be available in their booth, P-13, and also in the following presentations:

Transcatheter mitral valve therapies; new rings, anchors, and techniques
G. Nickenig, MD, May 21, Room Maillot at 8:40;

First-in-man of a transcatheter tricuspid valve in a severely regurgitant tricuspid valve patient.
J. Schofer, MD, May 21 Room 353 at 17:55;

Mitralign procedure a step-by-step case demonstration
G. Nickenig, MD, May 21, Room 242AB at 11:25;

Cardiovascular innovation pipeline – Mitral and tricuspid valve intervention
A. Groothuis, PhD, May 22, Room Maillot at 11:25.

The Mitralign Symposium, chaired by Azeem Latib, MD and Ted Feldman, MD, will occur on May 21st from 13:35-14:35 in room 241 at Les Palais des Congress. Georg Nickenig, MD will present “Mitralign CE mark six month data” and will be joined by Joachim Schofer, MD and Rebecca Hahn, MD providing their experience with the Mitralign Percutaneous Annuloplasty System for tricuspid regurgitation.

Mitralign is the only company to provide interventional cardiologists with the tools they need to perform minimally invasive, transcatheter procedures for both functional mitral regurgitation (FMR) and tricuspid regurgitation (TR). Unlike other approaches, the Mitralign Percutaneous Annuloplasty System uses wires and catheters to deliver pledgets to create plications and tighten the annulus, reduce valve circumference and bring the leaflets closer together. The company has developed an approach to treat both FMR and TR using the same innovative technology.

Mitralign continues to share clinical data and presentations on its advanced platform to treat both FMR and TR with its transcatheter-based solution. Additional data on the Mitralign Percutaneous Annuloplasty System will be presented in 2015 at the Transcatheter Valve Therapies (TVT) conference June 4-6 in Chicago and also at PCR London Valves from September 20-22 in Berlin.

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. Subsequent to 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 four million people in Europe and four 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, mitral regurgitation 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 TR². 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.

1. Jamieson WR, Edwards FH, Schwartz M, et al. Ann Thorac Surg 1999;67:943-951

2. Stuge O., Liddicoat J., et al. JTCS 2006;132:1258-61

3. Argarwal et al. Circ Cardiovasc Interv 2009;2:565-573

4. Rogers JH. Circulation 2009;119: 2718-25

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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