FOR IMMEDIATE RELEASE

ACC Data Supports Mitralign Transcatheter Tricuspid Repair

Mitralign Transcatheter Annuloplasty System could benefit 1.6 million U.S. patients

TEWKSBURY, MA – March 24, 2015 –Mitralign today highlighted a presentation by Prof. Dr. med. J. Schofer of the Medicare Center and Department for Percutaneous Interventions of Structural Heart Disease, Albertinen Heart Center, Hamburg at the recent American College of Cardiology (ACC) Scientific Sessions detailing his experience with the Mitralign Transcatheter Annuloplasty System. At ACC, Schofer discussed his successful use of the Mitralign System to perform a direct transcatheter annuloplasty on special access patients with tricuspid regurgitation (TR). The Mitralign system is not approved for sale or distribution however, it is currently being evaluated in clinical trials for an indication in functional mitral regurgitation.

Prof. Dr. med. J. Schofer performed the first direct transcatheter tricuspid annuloplasty at the Albertinen Heart Center in Hamburg, Germany in September 2014. "The first case we performed showed that we could safely implant this device while showing acute reduction in TR," said Schofer. "To date, the Mitralign System has been used in a total of five tricuspid cases at three centers with a 100% device implantation rate, acute TR reduction and no procedure or device related adverse events. "

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 (FMR) and functional tricuspid regurgitation (FTR). Unlike other approaches, the Mitralign Transcatheter Annuloplasty System uses wires and catheters to create plications that tighten the annulus, reduce valve circumference and bring the leaflets closer together. Mitralign has completed enrollment in clinical trials for a CE Mark indication for functional mitral regurgitation. The company has also developed a similar approach to treat tricuspid regurgitation using the same innovative technology, but with a modified delivery system.

"We are very pleased with the strong progress and early success of our transcatheter tricuspid program and we continue to strengthen our understanding of this new area in structural heart," commented Rick Geoffrion, chief executive officer of Mitralign. "The recent JACC publication[1] provides details on the first human experience in direct transcatheter tricuspid repair. Dr. Schofer's ACC presentation provided insights into additional successful procedures, indicating that we are on the right track to help address the tremendous interest in transcatheter therapies for direct repair of the tricuspid valve."

Over the next few months, Mitralign will offer presentations and updates on its advanced platform to treat both FMR and FTR with its transcatheter based solution. Additional data on the Mitralign Transcatheter Annuloplasty System will be presented in 2015 at EuroPCR, May 19-22 in Paris, the Transcatheter Valve Therapies (TVT) conference June 4-6 in Chicago and 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 and stretches the valve opening. The valve leaflets are not able to come together and close properly, allowing blood to flow, or regurgitate, back into the atrium. Consequences can include heart failure or serious rhythm problems called arrhythmias. There are an estimated 3.2 million patients with FMR in the USA. [3] If left untreated, FMR overloads the heart and can lead to or accelerate heart failure.

About Functional Tricuspid Regurgitation (FTR)

Functional tricuspid regurgitation occurs when the tricuspid valve fails to open and close properly, causing blood to flow backward into the right atrium. If left untreated, FTR can lead to heart enlargement and heart failure. In the U.S. alone, there are an estimated 1.6 million patients suffering from FTR[3]. It is estimated that 50% of patients with mitral regurgitation have moderate to severe tricuspid regurgitation.[2] FTR 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[3]. When treated, surgeons choose to repair 90% of the time over 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.

1. J Am Coll Cardiol. 2015:():. Doi:10.1016/j.jacc.2015.01.025
2. Topilsky Y, Nkomo VT, Vatury O, et al. Clinical outcome of isolated tricuspid regurgitation. J Am Coll Cardiol Img 2014;7:1185–94.
3. Acker MA, Bolling S, Shemin R, et.al., J Thorac Cardiovasc Surg 2006:132;568-77
4. Argarwal et al. Circ Cardiovasc Interv 2009;2:565-573

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