



**FOR IMMEDIATE RELEASE**

## **SCOUT I Study using Trialign™ System for Transcatheter Tricuspid Repair Shows Positive Outcomes**

*Data presented at TCT shows significant improvements in tricuspid regurgitation and patient quality of life*

WASHINGTON D.C. – November 1, 2016 –Mitralign today presented 30-day data from the SCOUT I Study designed to evaluate the performance of its Trialign™ System for tricuspid repair. The data was presented by Principal Investigator Rebecca T. Hahn, MD and showed positive data from the study's first 15 patient cohort.

The 30-day data, *Early Feasibility of a Percutaneous Tricuspid Valve Annuloplasty System for Symptomatic Chronic Functional Tricuspid Regurgitation: 30-Day Results From the SCOUT Trial* were presented by Dr. Hahn this morning at TCT in Washington, D.C. Results included 100% acute implant success, no deaths and no major adverse events (MAE) through 30 days, as well as statistically significant improvements in TV annulus area (from  $12.3 \pm 3.1$  cm<sup>2</sup> to  $11.3 \pm 2.7$  cm<sup>2</sup>,  $p=0.019$ ), PISA EROA (from  $0.51 \pm 0.2$  cm<sup>2</sup> to  $0.32 \pm 0.2$  cm<sup>2</sup>,  $p=0.020$ ), 6 minute walk test (from  $236.5m \pm 107.4$  to  $305.1m \pm 106.5$ ,  $p=0.003$ ) and Minnesota Living with Heart Failure Score, MLWHF, (from  $49.6 \pm 15.7$  to  $18.8 \pm 12.0$ ,  $p<0.001$ ).

“Trialign is the first transcatheter solution that has demonstrated promise in treating tricuspid regurgitation in an Early Feasibility Study,” stated Dr. Hahn. “Patients enrolled in this study reported feeling better at the 30 day time point and were able to complete more daily tasks than prior to the treatment, progress that was evidenced by multiple quality of life measures. That Trialign could have a 100% device implantation rate, acute TR reduction and no procedure or device related adverse events is a very strong indicator we are on the right track to help address the tremendous interest in transcatheter therapies for direct repair of the tricuspid valve.”

Trialign™ is designed to provide a non-surgical option for the treatment of tricuspid regurgitation for patients with symptomatic chronic functional tricuspid regurgitation. The device features an implant with a very small footprint designed for a versatile, customizable solution. Following the successful use of its technology in compassionate use cases in Europe, SCOUT I was initiated in the US to demonstrate early feasibility through an Investigational Device Exemption study.

“Our Trialign System is at the leading edge of possible solutions to treat an estimated 2.5 million patients suffering from TR in the U.S. alone,” said Rick Geoffrion, chief executive officer of Mitralign. “The tricuspid valve, often called the forgotten valve, is finally getting the transcatheter solution it needs and the attention it deserves.”

The Trialign™ System is an investigational device and is limited by Federal (or United States) Law to investigational use only. It is not available for sale or commercial distribution.

### **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 2.5 million patients suffering from TR<sup>1</sup>. It is estimated that 50% of patients with mitral regurgitation have moderate to severe tricuspid regurgitation<sup>2</sup>. The annual incidence of patients with TR is increasing with an estimated 220,000 patients in the US, and 330,000 patients in the EU developing moderate-severe TR each year<sup>1</sup>. Despite the large prevalence of patients, TR is generally untreated by surgery with approximately 10,000 tricuspid valve surgeries performed annually in the US<sup>3</sup>. Annuloplasty repair is the most used technique for tricuspid valve surgery and represents 90% of the current volume. Isolated tricuspid valve surgery is particularly rare representing only 10% of current procedures while the remaining 90% are performed in conjunction with other left-heart surgeries<sup>3,4</sup>.

### **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 tricuspid regurgitation. The company is a venture-backed, medical innovation company located near Boston, Massachusetts, USA. The Trialign System is an investigational device and is limited by Federal (or United States) Law to investigational use. The Mitralign Percutaneous Annuloplasty System (MPAS) received CE mark approval in February for the treatment of functional mitral regurgitation (FMR) and is not commercially available in the U.S.A. For more information, visit [www.mitralign.com](http://www.mitralign.com).

1. Tricuspid Regurgitation Global Strategic Market Assessment. Dymedex Consulting. 2016
2. Argarwal et al. Circ Cardiovasc Interv 2009;2:565-573
3. STS Adult Cardiac Surgery Database Executive Summary. 2014
4. Armen K. et al. Ann Thorac Surg. 2013;96:1546-52

###

Company Contact:  
David Schleifer  
Vice President of Marketing  
Mitralign Inc.  
+1 617.869.6166  
[dschleifer@mitralign.com](mailto:dschleifer@mitralign.com)