FOR IMMEDIATE RELEASE

Mitralign Completes Enrollment in First Phase of US Early Feasibility Study on Tricuspid Repair

The SCOUT Study evaluates the Trialign™System for transcatheter repair of functional tricuspid regurgitation (FTR)

TEWKSBURY, MA – July 13, 2016 – Mitralign, Inc., an innovative developer of transcatheter tricuspid and mitral valve repair solutions, announced today it has completed subject enrollment in the SCOUT, US early feasibility study.

"The completion of enrollment for this initial group of fifteen subjects is a significant milestone for the company and the industry. This is the first US early feasibility study to complete enrollment using a transcatheter device to treat the tricuspid valve. The SCOUT Study marks initiation of the path to evaluate catheter-based tricuspid repair for patients suffering from tricuspid regurgitation," said Rick Geoffrion, Chief Executive Officer of Mitralign. "We are pleased to announce we have also recently received approval to expand the study and enroll an additional cohort of subjects in the United States."

"The clinical community is excited about the potential opportunity to provide a breakthrough non-surgical option for patients with tricuspid regurgitation. We know the number of people suffering with tricuspid regurgitation is much bigger than previously reported, and we are in the nascent stages of treating this large, unaddressed population," commented Rebecca Hahn, M.D., Director of Interventional Echocardiography at NewYork-Presbyterian/Columbia University Medical Center and Principal Investigator for the SCOUT Study. "The Trialign System leaves behind a very small footprint, so we believe this device has the potential to be a front line solution for patients with functional TR."

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.

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[1].

It is estimated that 50% of patients with mitral regurgitation have moderate to severe tricuspid regurgitation[2]. 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[3]. Despite the large prevalence of patients, TR is generally untreated by surgery with approximately 10,000 tricuspid valve surgeries performed annually in the US[4]. 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[4, 5].

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. For more information, visit www.mitralign.com.

1. Stuge O., Liddicoat J., et al. JTCS 2006;132:1258-61
2. Argarwal et al. Circ Cardiovasc Interv 2009;2:565-573
3. Tricuspid Regurgitation Global Strategic Market Assessment. Dymedex Consulting. 2016
4. STS Adult Cardiac Surgery Database Executive Summary. 2014
5. Armen K. et al. Ann Thorac Surg. 2013;96:1546–52

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