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SCOUT I Study using Trialign™ System for Transcatheter Tricuspid Repair continues to show positive outcomes at 1 Year

12-month study data on first cohort of patients presented at TCT 2017

Denver, CO – November 1, 2017 – Mitralign, Inc., an innovative developer of transcatheter tricuspid and mitral valve repair solutions, today released 1 year follow up data from the SCOUT I Early Feasibility Study designed to evaluate the performance of its Trialign™ System. The data presented by Rebecca Hahn, M.D., New York-Presbyterian/ Columbia University Medical Center, continue to demonstrate clinically meaningful results from the study's first cohort, including sustained improvements at 1 year in NYHA status (90% in Class I/II) and Minnesota Living with Heart Failure Score, MLWHF, (from 49.6 ± 15.7 to 19.2 ± 12.4, p=0.003). Additional outcomes at 1 year include a 21% improvement in 6-minute walk test (from 236.5 ± 107.4 to 285.4 ± 115.5), a 21.6% reduction in PISA EROA from baseline, and a 17.1% improvement in LVOT Stroke Volume from baseline.

"The SCOUT I study is the first, Early Feasibility Study in the US with core lab adjudicated 1 year data showing long-term improvement in a population of subjects with severe, progressive TR." stated Dr. Rebecca Hahn. "Patients in the study continue to report feeling better which is supported by sustained improvement in multiple clinical and quality of life measures."

"One year is the benchmark for sustainability in a therapy and we are very pleased with the results," stated Rick Geoffrion, CEO of Mitralign. "As a leader in the transcatheter tricuspid space, we continue to show robust clinical data as we drive towards the commercialization of the product." The Trialign System is currently enrolling in the SCOUT I Early Feasibility Study and the SCOUT II CE Mark Study.

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[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[1]. Despite the large prevalence of patients, TR is generally untreated by surgery with approximately 10,000 tricuspid valve surgeries performed annually in the US[3]. 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[3, 4]. Permanent pacemaker (PPM) or implantable cardioverter defibrillator (ICD) lead placement has been shown to increase the frequency and/or severity of TR in multiple reports[5-11].

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 2016 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.

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