FOR IMMEDIATE RELEASE

Mitralign announces enrollment of first European subject in Transcatheter Tricuspid Repair Study enrolled in SCOUT II Study with Trialign™ System for Transcatheter Tricuspid Repair

The SCOUT II Study using the Trialign™ System has commenced at leading medical centers across Europe

TEWKSBURY, MA and Milan, Italy. – June 13, 2017 – Mitralign, Inc., an innovative developer of transcatheter tricuspid and mitral valve repair solutions, announced today the commencement of its SCOUT II study in Europe, with the Trialign System for the treatment of patients suffering from tricuspid regurgitation.

"We are pleased to be the first center in Europe to commence enrolling in SCOUT II," commented Azeem Latib, M.D., Interventional Cardiologist San Raffaele Scientific Institute, Milan, Italy. "This is an exciting therapy which allows us to deliver a minimally invasive solution to a group of patients who have limited treatment options. The procedure was a great success, as we saw acute reduction in tricuspid regurgitation and the patient was able to go home shortly thereafter."

"The tricuspid valve is the last major valve opportunity in the structural heart space," said Rick Geoffrion, Chief Executive Officer of Mitralign. "The 6-month data from our SCOUT I EFS Study in the United States has provided early safety and efficacy signals that we plan to build on with SCOUT II."

Additional SCOUT I data will be presented during the Satellite Symposium titled, Trialign: The Next Era in Tricuspid Repair, on Thursday, June 15, 2017 from 12:30-1:30 PM at the Transcatheter Valve Therapies (TVT) Conference in Chicago, IL: ***Sheraton Grand Chicago: Room Chicago VII.***

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

1. Tricuspid Regurgitation Global Strategic Market Assessment. Dymedex Consulting. 2016
2. Argarwal, S, et al. Interventional Cardiology Perspective of Functional Tricuspid Regurgitation. 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
5. Fanari Z. et al. The effects of right ventricular apical pacing with transvenous pacemaker and implantable cardioverter defibrillator on mitral and tricuspid regurgitation. *J Electrocardiol* 2015; 48: 791-797.
6. Sadreddini M, et al. Tricuspid valve regurgitation following temporary or permanent endocardial lead insertion, and the impact of cardiac resynchronization therapy. Open Cardiovasc Med J 2014; 8: 113-120.
7. Paniagua D. et al. Increased prevalence of significant tricuspid regurgitation in patients with transvenous pacemaker leads. Am J Cardiol 1998; 82: 1130-2.
8. Klutstein M, et al. Tricuspid incompetence following permanent pacemaker implantation. Pacing Clin Electrophysiol 2009: 32(Suppl 1): S135-7.
9. Kim JB, Spevack DM, Tunick PA, et al. The effect of transvenous pacemaker and implantable cardioverter defibrillator lead placement on tricuspid valve function: an observational study. J Am Soc Echo cardiogr 2008; 21: 284-7.
10. Mazine A, et al. Transvalvularpacemaker leads increase the recurrence of regurgitation after tricuspidvalve repair. Ann Thorac Surg 2013; 96: 816-22.
11. Alizadeh A, et al. Induction and aggravation of atrioventricular valve regurgitation in the course of chronic right ventricular apical pacing. Europace 2011; 13: 1587-90.

# # #

Company Contact:
David Schleifer
Vice President of Marketing
Mitralign Inc.
+1 617.869.6166
dschleifer@mitralign.com