FOR IMMEDIATE RELEASE

Mitralign Announces Enrollment of First U.S. Subject in Percutaneous Tricuspid Repair Study

Mitralign commences early feasibility study for tricuspid repair at leading medical centers in the United States

TEWKSBURY, MA – December 3, 2015 – Mitralign Inc. (Mitralign), a privately held medical device company, announced the first U.S. subject has been enrolled in the SCOUT Study using the company's Trialign™ (Percutaneous Tricuspid Valve Annuloplasty) System. The procedure was performed by Dr. Rebecca Hahn, Director of Interventional Echocardiography, Principal Investigator for the SCOUT study and Dr. Susheel Kodali, Interventional Cardiologist and Director, Structural Heart and Valve Program at NewYork-Presbyterian/Columbia University Medical Center.

"We are extremely excited to be pioneering a novel solution in percutaneous repair for the tricuspid valve," commented Dr. Hahn. "Given the reports that operative mortality for tricuspid valve replacement (TVR) surgery can top 30%[1], coupled with the lack of treatment options, this system represents a very welcome advancement."

SCOUT is a U.S. based early feasibility Investigational Device Exemption study using the Trialign system in subjects with symptomatic chronic functional tricuspid regurgitation (FTR). It will assess the early safety and feasibility of the device for the treatment of tricuspid regurgitation in subjects with a minimum of moderate tricuspid regurgitation and in whom left-sided valve surgery is not planned.

"An estimated 1.6 million patients suffer from tricuspid regurgitation in the U.S.[2], yet little progress has been made developing tricuspid specific therapies," stated Rick Geoffrion, chief executive officer of Mitralign. "We are proud to be at the forefront of transcatheter repair for tricuspid regurgitation."

About Functional Tricuspid Regurgitation (FTR) Tricuspid regurgitation, sometimes called tricuspid insufficiency, occurs when the tricuspid valve fails to open and close properly, causing blood to flow backwards into the right atrium. It is estimated that 50% of patients with mitral regurgitation have moderate to severe tricuspid regurgitation[3]. However, in the U.S., surgeons treat only 5,500 patients per year, most of them in conjunction with left heart surgeries[4]. When treating the valves, surgeons choose repair 90% of the time versus replacement 10%[4]. If left untreated, TR can weaken the heart leading to heart enlargement and ultimately progressing to heart failure.

About Mitralign Inc.

Mitralign Inc. is the valve repair company with a transcatheter direct annuloplasty system designed to treat both functional mitral regurgitation and functional tricuspid regurgitation. The system is not available for commercial use. The company is a venture-backed, medical innovation company located near Boston, Massachusetts, USA. For more information, visit www.mitralign.com.

1. Leviner DB et al, J Heart Valve Dis. 2014;23:209
2. Stuge O., Liddicoat J., et al. JTCS 2006;132:1258-61
3. Argarwal et al. Circ Cardiovasc Interv 2009;2:565-573
4. Rogers JH. Circulation 2009:119: 2718-25

# # #

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