**FOR IMMEDIATE RELEASE**

# Mitralign Raises $40M in Equity Financing

## Funding will support clinical studies of Trialign™ System for tricuspid repair in US and EU and commercial launch activities of mitral repair system in Europe

TEWKSBURY, MA – May 16, 2016 – Mitralign, Inc., an innovative developer of direct transcatheter mitral and tricuspid valve repair solutions, announced today it has raised $39.8 million to date in a Series E equity round of financing. With the Series E financing raised, the Company plans to continue growing its platform by pursuing US and CE regulatory approval for the commercialization of their Trialign system in parallel with preparations for commercial launch in Europe of their Mitralign Percutaneous Annuloplasty System (MPAS).

"The funding reinforces the importance of developing distinctly new tricuspid treatment options and it validates our transcatheter valve repair platform strategy. The capital will be used to accelerate clinical trials both in the United States and in Europe for the Trialign System and support our leadership in the tricuspid space" said Rick Geoffrion, chief executive officer of Mitralign. "We look forward to the approaching completion of the SCOUT early feasibility study in the US and the initiation of the SCOUT II Study to support the CE Mark in Europe as we expand our tricuspid clinical data set."

Both the Trialign and MPAS Systems feature a customizable therapy solution in concert with an extremely small footprint, which leaves all clinical options open for the physician, a key consideration for a front line intervention. The Trialign System is currently enrolling patients in an early feasibility IDE study in the US and is not approved for sale or distribution. The MPAS received CE mark approval in February for the treatment of functional mitral regurgitation (FMR).

**About Functional Tricuspid Regurgitation (FTR)**

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 US alone, there are at least 1.6 million patients suffering from moderate/severe TR[1]. It is estimated that at least 50% of patients with mitral regurgitation have moderate to severe tricuspid regurgitation[2]. TR is currently undertreated by surgery. According to one study, surgeons in the US treat only 5,500 patients per year, most of them in conjunction with left heart surgeries. When treating the valves, surgeons choose repair 90% of the time versus replacement (10%)[3].

**About Functional Mitral Regurgitation (FMR)**

The mitral valve controls blood flow from the left atrium to the left ventricle of the heart, allowing blood to flow in one direction through the heart and into the body. Functional Mitral Regurgitation (FMR) is the most common valve disease and occurs when the left ventricle of the heart is enlarged and stretches the valve open. Subsequent to this remodeling, the valve leaflets are not able to come together and close properly, allowing blood to flow, or regurgitate, backwards into the atrium. Consequences can include heart failure or serious rhythm problems called arrhythmias. An estimated four million people in Europe and four million people in the United States have significant mitral valve insufficiency, also known as mitral regurgitation, with an annual incidence of 250,000[4]. If left untreated, mitral regurgitation overloads the heart and can lead to or accelerate heart failure.

**About Mitralign Inc.**

Mitralign Inc. is the valve repair company with the only transcatheter direct annuloplasty system designed to treat both functional mitral regurgitation and tricuspid regurgitation. The company, a leader in transcatheter repair for tricuspid regurgitation 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. Rogers JH.Circulation2009:119: 2718-25
3. Agarwal et al. Circ Cardiovasc Interv 2009;2:565-573
4. Jamieson WR, Edwards FH, Schwartz M, et al. Ann Thorac Surg 1999;67:943-951

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