FOR IMMEDIATE RELEASE

Mitralign Percutaneous Annuloplasty System Earns CE Mark Approval for Functional Mitral Regurgitation

WASHINGTON D.C. and TEWKSBURY, MA – February 22, 2016 –Mitralign, Inc., an innovative developer of direct transcatheter mitral and tricuspid valve repair solutions, today announced its Mitralign Percutaneous Annuloplasty System (MPAS) has received CE mark approval from its notified body, the British Standards Institution (BSI), for the treatment of functional mitral regurgitation (FMR). This confirmation offers a unique new treatment alternative for patients with symptomatic functional mitral valve regurgitation. CE mark approval allows the company to market the Mitralign System in the European Union.

"The data show treatment with the Mitralign System is safe in FMR patients." said Prof. Georg Nickenig of the University of Bonn. "Due to its versatility and small footprint, the device can be considered a front-line treatment option for patients with mitral regurgitation."

Data from the CE mark study demonstrated the Mitralign System met both its 30 day safety and its six month performance endpoints. In the prospective, multi-center, single arm study, patients treated with the Mitralign System demonstrated statistically significant ($p<0.05$) improvements in 6 minute walk test, left ventricular dimensions and remodeling; reversing the course of heart dilation due to heart failure.

"The CE mark for FMR is the first approved indication for the Mitralign platform and it provides clear validation of the technology," stated Rick Geoffrion, chief executive officer of Mitralign. "This key accomplishment lends momentum to our efforts with physicians and regulatory agencies to continue to study our platform, including the Trialign™ System for tricuspid repair."

Mitralign is the only company to provide a direct transcatheter annuloplasty system designed to treat both functional mitral regurgitation (FMR) and tricuspid regurgitation (TR). Both the Mitralign and Trialign Systems feature a customizable therapy solution in concert with an extremely small footprint that leaves all clinical options open for the physician. MPAS is not available for sale in the USA. The Trialign System is currently enrolling patients in an early feasibility IDE study in the USA and is not approved for sale or distribution.

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[1]. If left untreated, mitral regurgitation overloads the heart and can lead to or accelerate heart failure.

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[2]. It is estimated that 50% of patients with mitral regurgitation have moderate to severe tricuspid regurgitation[3]. TR is currently undertreated by surgery. In the U.S. surgeons 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%)[4].

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.

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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.Circulation2009:119: 2718-25

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