



**FOR IMMEDIATE RELEASE**

## **Mitralign Confirms First-In-Man Percutaneous Tricuspid Repair**

***Non-surgical option for tricuspid regurgitation could benefit 1.6 million U.S. patients***

**LONDON, UK and TEWKSBURY, MA – September 29, 2014** –Mitralign Inc., a cardiovascular device company, today reported on the successful use of its technology to perform a percutaneous repair on a patient with tricuspid regurgitation (TR). Prof. Dr. med. J. Schofer of the Medicare Center and Department for Percutaneous Interventions of Structural Heart Disease, Albertinen Heart Center, Hamburg and Rebecca Hahn, MD, Director of Interventional Echocardiography, Columbia University Medical Center / New York Medical Center / New York Presbyterian Hospital presented at the PCR London Valves Conference and detailed the procedure; a percutaneous bicuspidization of the tricuspid valve, successfully converting a regurgitating tri-leaflet valve into a functioning bi-leaflet valve. The German regulatory body BfArM approved the patient for a compassionate use exemption, as no other options were available. The successful procedure was performed at the Albertinen Heart Center in Hamburg, Germany. The Mitralign product is currently being evaluated in clinical trials for an indication in functional mitral regurgitation. The device is not approved for sale or distribution.

“We continue to see more and more patients presenting with tricuspid regurgitation and to date, we have not had an interventional device available to treat these patients,” commented Prof. Dr. med. J. Schofer. “This is perhaps the most important intervention I have ever performed. It is the very first percutaneous tricuspid annuloplasty and it was performed successfully; dramatically reducing TR with a single small implant and improving the outcome for a patient who would have had a 30% chance of mortality with surgery<sup>1</sup>. I expect that in the future, this will become an outpatient procedure as we start to treat more and more patients in this manner.”

“Current 2D and 3D echo imaging technologies allow us to easily and accurately place the implant in the correct location,” stated Rebecca Hahn, MD, “and then immediately see dimensional changes in the valve once the procedure is completed.”

<sup>1</sup> Nath JACC 2004; 43: 405-9

Tricuspid regurgitation occurs when the tricuspid valve fails to open and close properly, causing blood to flow backward into the right atrium. If left untreated, TR can lead to heart enlargement and heart failure. The traditional solution for TR is optimized medical therapy or in some cases an open-heart surgical procedure. In the U.S. alone, there are an estimated 1.6 million patients suffering from TR<sup>1</sup>. It is estimated that 50% of patients with mitral regurgitation have moderate to severe tricuspid regurgitation.<sup>1</sup> TR is currently undertreated by surgery. In the U.S. surgeons treat only 8,000 patients per year, most of them in conjunction with left heart surgeries<sup>2</sup>. When treated, surgeons choose to repair 90% of the time over replacement (10%)<sup>3</sup>.

“Tricuspid valve disease can have serious implications for the patient, yet it is rarely treated by surgeons, who tend to prioritize the mitral valve for primary surgical treatment,” said Rick Geoffrion, chief executive officer of Mitralign. “Our technology can eliminate the need to choose one valve over the other; enabling a physician to successfully treat the tricuspid valve without open heart surgery and mimic a surgical repair procedure (Kay Bicuspidization) that has good long-term data.”

#### **About Mitralign Inc.**

Mitralign Inc. is a venture-backed, medical device company located near Boston, Massachusetts, USA. Mitralign has developed a percutaneous technology that emulates surgical annuloplasty, the surgical repair of leaking heart valves. For more information, visit [www.mitralign.com](http://www.mitralign.com).

<sup>1</sup> Stuge O., Liddicoat J., et al. JTCS 2006;132:1258-61

<sup>2</sup> Argarwal et al. Circ Cardiovasc Interv 2009;2:565-573

<sup>3</sup> Rogers JH. Circulation 2009;119:2718-25

# # #

Company Contact:  
David Schleifer  
Director of Marketing  
Mitralign Inc.  
+617.869.6166  
[dschleifer@mitralign.com](mailto:dschleifer@mitralign.com)