

## **Tendyne Announces Successful First Human Implants of the Tendyne Transcatheter Mitral Valve Implant (TMVI)**

ROSEVILLE, Minn., Dec. 2, 2014 /PRNewswire/ -- Tendyne Holdings, Inc. ("Tendyne"), a privately held clinical stage medical device company, announced today that the Tendyne Transcatheter Mitral Valve system has been successfully implanted in three patients. Mr. Neil Moat, a leading expert in mitral valve surgery and TAVI, performed the procedures at the Royal Brompton Hospital in London, England under a compassionate use protocol in October and early November. The patients had severe mitral regurgitation that was eliminated after the procedure was performed via a trans-apical approach without cardio-pulmonary bypass (known as a trans-catheter mitral valve implantation, or TMVI).

Commenting on the procedures, Mr. Moat said, "The first patient, a 68 year old female with severe left ventricular dysfunction and severe functional (secondary) mitral regurgitation, was not considered a candidate for conventional mitral valve surgery at another UK centre. Last month, using a transapical approach, we deployed the Tendyne device, optimizing its placement to eliminate mitral regurgitation." In the second procedure, Mr. Moat stated, "We implanted the Tendyne device in a 85 year old man with prior CABG and significant renal dysfunction who had severe degenerative mitral regurgitation with chordal rupture and leaflet prolapse. The procedure went smoothly and the patient had no residual mitral regurgitation. A third patient (age 87) with severe degenerative primary mitral regurgitation recently received this novel device at the Royal Brompton, resulting in no residual mitral regurgitation and improved hemodynamics. All 3 patients made a rapid recovery with no major in-hospital complications. All the patients have been discharged to their own homes."

The Tendyne TMVI is a fully retrievable and repositionable, apically tethered tri-leaflet porcine pericardial valve sewn onto a Nitinol frame that was specifically designed to address the complex mitral anatomy of functional, degenerative and mixed etiology mitral regurgitation. Left untreated, mitral regurgitation can lead to heart failure and death.

"The use of the Tendyne valve under a compassionate use protocol is a significant milestone for Tendyne," said Jeff Franco, Chief Executive Officer of Tendyne. "Multiple sizes and the flexibility associated with the tether allowed us to treat a wide array of patients. We look forward to continuing to implant the device in a multi-national feasibility study as we move towards regulatory approval. We are one step closer to offering a safe, effective, and minimally invasive option to the millions of patients with mitral regurgitation."

### **About Tendyne**

Tendyne Holdings, Inc, headquartered in Roseville, MN, is a private medical device company developing a unique Transcatheter Mitral Valve Implant (TMVI). Implanted in a beating heart in a hybrid operating room, the Tendyne design has proprietary and patented features that can treat a variety of mitral pathologies. With a less invasive approach than open cardiac surgery, TMVI may result in similar outcomes with fewer surgical complications.

[www.tendyne.com](http://www.tendyne.com)

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