

Tendyne Announces First Enrollment in TMVI Clinical Trial

ROSEVILLE, Minn., Dec. 15, 2014 /PRNewswire/ -- Tendyne Holdings, Inc. ("Tendyne"), a privately held clinical stage medical device company, announced today that in November 2014 the Tendyne Transcatheter Mitral Valve Implantation system (TMVI) was successfully implanted in the first patient of the Tendyne Feasibility Study. This was the first patient enrolled in a three continent, multicenter trial, which aims to generate insight into the safety and performance of the Tendyne device in inoperable patients suffering from mitral regurgitation.

Dr. David Muller and Dr. Paul Jansz performed the implantation at St. Vincent's Hospital in Sydney, Australia. Commenting on the procedure Dr. Muller said, "The device was implanted transapically without cardiopulmonary bypass and performed as intended by completely eliminating mitral regurgitation. The patient recovered quickly and was released from the hospital on day 5. We are now monitoring the patient as part of the Tendyne feasibility study. We believe the device has the potential to offer a very effective solution for patients at high risk for conventional mitral valve surgery".

Tendyne CEO Jeff Franco said, "Enrolling patients in a prospective clinical study is an important milestone for Tendyne. We look forward to more clinical activity as we treat inoperable patients suffering from functional, degenerative and mixed etiology mitral regurgitation. Tendyne is pursuing government and Ethics Committee approvals to further the Feasibility Study which is an interim step on the path to eventual regulatory approval."

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.

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

CONTACT: Mr. Jeff Franco, President & Chief Executive Officer, Tendyne Holdings, Inc., (651) 289-5500