VDYNE Announces First Patient Enrolled in VISTA US Early Feasibility Study for the Treatment of Tricuspid Regurgitation

VDYNE initiates US early feasibility study evaluating the VDYNE Transcatheter Tricuspid Valve Replacement System for the treatment of tricuspid regurgitation

MAPLE GROVE, MINNESOTA, USA, April 9, 2024 /EINPresswire.com/ -- VDYNE Announces First Patient Enrolled in VISTA US Early Feasibility Study of the VDYNE Transcatheter Tricuspid Valve for the Treatment of Tricuspid Regurgitation

VDYNE, Inc. ("VDYNE" or “the Company”), a privately held medical device company developing transcatheter heart valve replacement technologies for the treatment of tricuspid regurgitation, announced today that it has initiated its United States early feasibility study, called VISTA-US, to evaluate the clinical safety and performance of the VDYNE Transcatheter Tricuspid Valve Replacement System for the treatment of tricuspid regurgitation.

The first patient enrolled in the VISTA-US study was treated by Drs. Paul Sorajja, Vinayak Bapat and Nadira Hamid at the Minneapolis Heart Institute Foundation (“MHIF”) in Minneapolis, Minnesota, USA. The patient was successfully implanted with the VDYNE tricuspid valve with regurgitation reduced to none and no paravalvular leakage immediately post-procedure.

“Following our previous experience with the VDYNE Valve System under a compassionate use protocol, we are very pleased to initiate VDYNE’s VISTA-US feasibility study,” said Dr. Paul Sorajja, Roger L. and Lynn C. Headrick Family Chair for the MHIF Valve Science Center. He added, “The VDYNE System’s unique deployment and securement features, together with a streamlined implantation procedure enabled the patient to quickly transition from the procedure to the recovery ward. We look forward to helping advance this new therapy for patients suffering from tricuspid regurgitation.”

The initiation of the Company’s VISTA-US study expands the ongoing clinical studies aimed at assessing the safety and effectiveness of the VDYNE Transcatheter Tricuspid Valve Replacement System. The Company previously initiated a global (non-US) feasibility study – called VISTA - which is a single arm study enrolling up to forty (40) patients suffering from moderate or greater tricuspid regurgitation in up to twenty (20) sites across Europe and Australia. To date the Company has successfully completed eleven (11) clinical cases under VISTA across seven (7) clinical sites in Australia and Europe and is targeting commencing an expanded clinical study to

support CE Marking at the end of 2024.

“With both a global and US feasibility study now underway, more than 25 clinical cases completed, and a fast device procedure time, VDYNE is well-placed in its goal of advancing the VDYNE Valve System as a treatment option for the millions of patients afflicted by the debilitating effects of tricuspid regurgitation. We are very grateful to the team at MHIF and all our physicians in the United States, Australia and Europe for their expertise and assistance,” commented David McIntyre, Chairman of VDYNE.

The VISTA-US clinical trial aims to enroll up to thirty (30) patients with severe tricuspid regurgitation of primary or secondary etiology at a maximum of ten (10) clinical sites across the United States (clinicaltrials.gov: NCT05848284). The VDYNE Valve System has previously been granted FDA Breakthrough Device Designation.

The VDYNE Valve System is the world’s only transcatheter tricuspid valve replacement system incorporating “side-delivery” which, prior to implantation, compresses the valve vertically (instead of horizontally) thereby allowing the Company to deliver a broad range of valve sizes through a single 28 french catheter. VDYNE believes that its proprietary side-delivery system has the potential to be used in a broad range of patient anatomies with a fast, easy-to-use implantation procedure.

About VDYNE, Inc.

VDYNE is a privately held medical device company pioneering an innovative interventional valve replacement technology designed to treat tricuspid regurgitation. VDYNE is based in Maple Grove, Minnesota.

The VDYNE Tricuspid Valve Replacement System is under clinical investigation and is not commercially available in the United States of America, or elsewhere.

Details of VISTA-US can be found at:
https://clinicaltrials.gov/study/NCT05848284?spons=VDyne,%20Inc.&rank=1

About Tricuspid Regurgitation

Tricuspid regurgitation occurs when the tricuspid heart valve does not close properly, and blood flows backwards from the right ventricle into the right atrium instead of progressing through the heart to the lungs for re-oxygenation. This regurgitation is a debilitating condition that impacts the general health and quality of life of a significant portion of the patient population.

For more information please email investor@vdyne.com

Investor Relations

VDYNE, Inc.
investor@vdyne.com
