VDYNE Announces 1st Patient Enrolled in VISTA Global Clinical Study for the Treatment of Tricuspid Regurgitation

MAPLE GROVE, MINN, USA, April 18, 2023 /EINPresswire.com/ -- VDYNE, Inc. ("VDYNE" or "the Company"), a privately held medical device company developing transcatheter valve technologies for the treatment of tricuspid regurgitation, announced today that it has initiated its global feasibility study – called VISTA – to evaluate the VDYNE transcatheter tricuspid valve for the reduction of moderate to severe tricuspid valve regurgitation.

The first patient enrolled in the Company's VISTA study was treated by Dr David Muller and Dr Paul Jansz at St. Vincent's Hospital in Sydney, Australia. The patient was successfully implanted with the VDYNE tricuspid valve and left the operating theater in a stable condition with no paravalvular leaks and was discharged from hospital six days after the surgery.

"We are very pleased to offer a minimally invasive, non-surgical, therapy to a highly complex patient with multiple co-morbidities, who was suffering from the debilitating effects of tricuspid regurgitation" said Dr David Muller. He added: "The implant was completed with a short device treatment time of only two hours enabling the patient to quickly transition out of the operating theater with no residual valve regurgitation and no complications. VDYNE's tricuspid valve offers the promise of improving the quality of life of patients with limited or no treatment options".

Tricuspid regurgitation is a condition when the tricuspid valve's flaps (or leaflets) do not close properly. The tricuspid valve controls the flow of blood from the heart's right atrium to the right ventricle. When the right ventricle of the heart endeavours to pump blood from the heart to the lungs for re-oxygenation, an impaired tricuspid valve allows blood to flow back or "leak" from the right ventricle into the right atrium leading to shortness of breath, fatigue, abnormal heart performance and an enlarged heart. VDYNE's minimally invasive delivery system delivers a

prosthetic valve via a transfemoral catheter to replace the body's "leaky valve". The novel design of the VDYNE valve and delivery system is expected to provide a treatment solution for a large range of tricuspid anatomies as compared to existing technologies.

"The commencement of the VISTA global feasibility study marks the next step in the Company's clinical development and follows the treatment of a diverse group of patients under compassionate use. With the benefit of FDA confirmation of Breakthrough Device Designation, VDYNE is also in the advance stages of preparing to initiate an early feasibility study in the United States", commented David McIntyre, Chairman of VDYNE.

The VISTA global feasibility study is a single arm study assessing forty (40) patients suffering from moderate to severe tricuspid regurgitation in twenty (20) sites across the European Union, Canada and Australia.

The VDYNE tricuspid valve was also previously granted U.S. Food and Drug Administration ("FDA") Breakthrough Device Designation and is indicated for percutaneous tricuspid reduction of symptomatic tricuspid valve regurgitation in patients who have been determined to be at prohibitive risk for tricuspid valve surgery by a heart team.

About VDYNE Inc

VDYNE is a privately held medical device company pioneering an innovative interventional valve replacement technology for the treatment of tricuspid regurgitation. VDYNE is based in Maple Grove, Minneapolis.

The VDYNE tricuspid valve replacement system is under clinical investigation and is not commercially available in the United States of America, or elsewhere.

About Tricuspid Regurgitation

Tricuspid regurgitation occurs when the tricuspid 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. More importantly, surgical intervention to treat tricuspid regurgitation has high rates of mortality and morbidity. There are presently no approved minimally invasive valve replacement treatment alternatives.

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