VDYNE to Present VISTA Study Data at 2025 EuroPCR Conference

VDYNE to present joint data from the Company's VISTA-Global and the VISTA-US Early Feasibility Study at the EuroPCR meeting in Paris, France on May 22, 2025

MAPLE GROVE, MN, UNITED STATES, May 13, 2025 /EINPresswire.com/ -- VDYNE, Inc. ("VDYNE" or "the Company"), a privately held medical device company developing transcatheter valve replacement technologies for the treatment of tricuspid regurgitation, announced today that the Company will present joint data from the Company's VISTA-Global Early Feasibility Study (EFS) and the VISTA-US Early Feasibility Study at the EuroPCR meeting to be held in Paris, France.

The presentation, titled "Transcatheter Tricuspid Valve Implantation Using the VDYNE System" will be presented on behalf of all VISTA study investigators by Dr. Joerg Kellermair from the Johannes Kepler University, Linz, Austria at 8:30am (Central European Summer Time) on Thursday, May 22nd, 2025.

"VDYNE is thrilled to provide the first release of clinical data that has been collected across the Company's global VISTA studies in more than thirty (30) sites around the world" said Dr. Vinny Podichetty, Vice President – Clinical Affairs at VDYNE. "Dr. Kellermair's presentation will showcase a significant body of clinical data and provide an insight into our broadening clinical experience and strong patient outcomes with our novel valve and side-delivery technology. This is an incredible milestone for the Company ahead of the forthcoming commencement of our U.S. pivotal study".

The VISTA-Global and VISTA-US Early Feasibility Studies are two prospective, single-arm, multi-center global studies in fifteen (15) countries evaluating the safety and performance of the VDYNE Tricuspid Valve Replacement System (VDYNE Valve System) in patients with symptomatic severe tricuspid regurgitation. Endpoints include device and / or procedure related Major

Adverse Events at thirty (30) days for safety, and reduction in tricuspid regurgitation, changes in New York Heart Association (NYHA) class status, 6-minute walk distance and Kansas City Cardiomyopathy (KCCQ) Questionnaire for efficacy.

Since introducing the Company's final design into the clinical setting in November 2023, VDYNE has treated more than sixty (60) cases under the VISTA-US Study, the VISTA-Global Study and other protocols. VDYNE is presently advancing its registrational study to support CE Marking, and with the benefit of having been previously granted U.S. Food & Drug Administration (FDA) FDA Breakthrough Device Designation, the Company expects to shortly initiate a pivotal study to support pre-market approval of the VDYNE Valve System in the United States.

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.

For more information please email:

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