JenaValve Technology Initiates U.S. Patient Enrollment in Early Feasibility Study of Next-Generation TAVR System for the Treatment of Severe Aortic Stenosis and Severe Aortic Regurgitation

Successful Implantations Completed with Everdur™ Transcatheter Valve and Coronatix™ Transfemoral Delivery Catheter at Columbia University Medical Center and MedStar Washington Hospital

Irvine, California – August 3, 2018 – JenaValve Technology, Inc., a developer and manufacturer of differentiated transcatheter aortic valve replacement (TAVR) systems, today announced initiation of patient enrollment in the Early Feasibility Study (EFS) of its next generation JenaValve Pericardial TAVR System using the Everdur™ transcatheter heart valve (THV) and Coronatix™ Transfemoral Delivery Catheter at NewYork-Presbyterian/ Columbia University Medical Center (CUMC), New York City, and MedStar Washington Hospital Center, Washington, DC. The EFS is investigating the JenaValve Pericardial TAVR System for the minimally invasive treatment of patients with symptomatic, severe aortic stenosis (AS) and symptomatic, severe aortic regurgitation (AR) for whom open surgery is an extreme or high risk. The JenaValve Pericardial TAVR System is an investigational device in the United States and internationally.

The EFS is a prospective, single-arm study of the JenaValve Pericardial TAVR System being conducted at several centers of excellence in the United States under an FDA-approved investigation device exemption (IDE). It is part of a larger, ongoing CE Mark clinical program investigating the JenaValve Pericardial TAVR System for the same indications at centers in Europe and New Zealand.

The JenaValve system is proprietary and differentiated from currently available TAVR devices due to the Everdur THV locator-based technology, designed to enable anatomically-correct, predictable implantation using the new 18-Fr equivalent Coronatix Transfemoral Delivery Catheter. Enrollment has been completed for the AS CE Mark clinical program and is ongoing for the AR CE Mark clinical program.

The Executive Chair of the JenaValve Clinical Development Program Dr. Martin Leon (Director of the Center for Interventional Vascular Therapy and Professor of Medicine at CUMC) said, “Both myself and my CUMC colleagues, Dr. Susheel Kodali and Dr. Torsten Vahl, are extremely pleased to be the first U.S. physicians to treat patients with the new JenaValve TAVR system. The first procedures for both AS and AR patients demonstrated the system’s ease of use and potential that the Everdur valve may be an important addition to the transcatheter valve products. In particular, the JenaValve TAVR technology enables TAVR treatment for patients with severe AR who are at increased surgical risk that until now have not had a suitable transcatheter option in the U.S. We look forward to continuing our work with the JenaValve clinical and product development teams to expand the study of its TAVR technology in the U.S.”

"It has been our goal since the early development of our next generation TAVR System to bring this novel technology into the United States," said JenaValve Chief Executive Officer Victoria Carr-Brendel, PhD. "We are greatly encouraged to initiate enrollment at these prestigious centers under the direction of these physicians, and thank them for their efforts. We will continue to work tirelessly with our clinical partners to expand patient enrollment at new clinical sites in the United States."

The Company is seeking FDA approval for expanded IDE access to patients at the top clinical centers in the U.S.

About JenaValve Transfemoral TAVR System

The JenaValve Pericardial TAVR System consists of the Everdur™ Pericardial Aortic Valve (manufactured at the JenaValve England facility) and the Transfemoral Delivery System. The bioprosthesis comprises a self-expanding nitinol stent with a porcine pericardial valve manufactured using state-of-the-art tissue processing techniques. The Coronatix™ transfemoral delivery catheter is designed to deliver the bioprosthesis using a simple stepped approach with anatomic positioning over the native valve. The System is available in three sizes intended for aortic annulus diameters from 21mm to 27mm. A larger bioprosthesis size is in development.

About JenaValve

JenaValve Technology, Inc., with locations in Irvine, California, Leeds, England, and Munich, Germany, develops, manufactures and markets transcatheter aortic valve replacement (TAVR) systems to treat patients suffering from aortic valve disease. The Company is in clinical development of its next generation transfemoral TAVR system, consisting of the Everdur™ valve and Coronatix™ transfemoral delivery catheter, in both the U.S. and CE Mark countries for treating patients with aortic stenosis and/or aortic regurgitation. The Company's first generation transapical system, consisting of the JenaValve™ valve with Cathlete PLUS™ delivery system, was commercialized under CE Mark approval for aortic valve stenosis and for aortic valve regurgitation. JenaValve is backed by world-class U.S., European and Asian investors, including Andera Partners (formerly Edmond de Rothschild Investment Partners), Gimv (a Euronext-listed investment company - ticker: GIMB), Legend Capital, NeoMed Management, Omega Funds, RMM, Valiance Life Sciences and VI Partners. Additional information is available at www.jenavalve.com.

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Investor and Media Contact:
Matt Clawson
W2O Group
(949) 370-8500
mclawson@w2ogroup.com