JenaValve Technology Receives FDA Approval for Expanded IDE Enrollment in the Treatment of Patients with Severe Aortic Stenosis and Severe Aortic Regurgitation

Up to 80 patients (40 aortic stenosis and 40 aortic regurgitation) at 10 sites approved for treatment in the U.S.

Irvine, California – December 3, 2018 – JenaValve Technology, Inc., a developer and manufacturer of differentiated transcatheter aortic valve replacement (TAVR) systems, today announced U.S. Food and Drug Administration (FDA) approval of expansion of its Investigational Device Exemption (IDE) feasibility studies for the JenaValve Pericardial TAVR System with the Everdur™ transcatheter heart valve (THV) and Coronatix™ Transfemoral Delivery Catheter. The approval expands eligible patient enrollment from 20 patients at extreme or high surgical risk (10 aortic stenosis [AS], 10 aortic regurgitation [AR]) to 80 patients at extreme or high surgical risk (40 AS, 40 AR) at up to 10 U.S. sites.

The prospective IDE studies are part of a larger, ongoing CE Mark clinical program investigating the JenaValve Pericardial TAVR System for the same indications at centers of excellence 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 Columbia University Medical Center) said, "We were the first to perform this procedure in the U.S., and have been impressed with the performance of both the delivery system and the valve. We, along with our colleagues at MedStar Washington Hospital Center, conducted the initial U.S. clinical cases in patients with both AS and AR, and believe that those results warrant expanded investigation of the system in the United States. We are especially encouraged by the JenaValve TAVR technology in the minimally invasive treatment of eligible patients with severe AR who are at increased surgical risk. That group of patients, until now, have been wihout a suitable transcatheter option in the U.S. We look forward to welcoming the new sites and physicians into the studies, and continuing to study the versatility and durability of the JenaValve implants."

"We are extremely pleased with the initial clinical results, and are grateful to the U.S. physicians who made these trials possible as they seek a less invasive approach for these patient populations," said JenaValve Chief Executive Officer Victoria Carr-Brendel, PhD. "The device continues to demonstrate exceptional hemodynamics and best-in-class perivalvular leakage results with low pacemaker rates. We are all encouraged by the

FDA's approval to expand this U.S. clinical program and look forward to furthering our partnership with clinical leaders in the United States."

JenaValve is currently seeking CE Mark approval for the treatment of patients with symptomatic, severe aortic stenosis, and anticipates commercializing the system in select countries and sites in 1H 2019.

About JenaValve Transfemoral TAVR System

The JenaValve Pericardial TAVR System consists of the Everdur™ Pericardial Aortic Valve (manufactured at the JenaValve facility in the U.K.) 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. The JenaValve Pericardial TAVR System is an investigational device in the United States and internationally.

About JenaValve

JenaValve Technology, Inc., with locations in Irvine, California, Leeds, U.K, 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. JenaValve is backed by 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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