JenaValve Technology Implants Initial Patients in CE Mark Study for the Treatment of Severe Aortic Regurgitation with Next-Generation TAVR System

Initial Enrollment Yields Successful Implantation with Everdur™ Transcatheter Valve and Advanced Coronatix™ Transfemoral Delivery Catheter

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IRVINE, Calif.--(BUSINESS WIRE)--JenaValve Technology, Inc., a developer and manufacturer of differentiated transcatheter aortic valve replacement (TAVR) systems, today announced initiation of patient enrollment and implantations associated with the CE Mark study of its next generation JenaValve Pericardial TAVR System using the Coronatix™ Transfemoral Delivery Catheter for the percutaneous treatment of patients with symptomatic, severe aortic regurgitation (AR). The JenaValve Pericardial TAVR System is an investigational device in the United States and internationally.

The CE Mark study is an international, prospective, non-randomized, single-arm trial of the JenaValve Pericardial TAVR System for the treatment of AR in patients who are at increased risk for conventional surgical valve replacement.

The JenaValve system is proprietary and differentiated from currently available TAVR devices due to the Everdur™ locator-based technology, designed for more predictable implantation using the new 18-Fr equivalent Coronatix Transfemoral Delivery Catheter. The optimized TAVR system has now been used to treat several AR patients in Germany.

The national Principal Investigator, Prof. Dr. med. Stephan Baldus (Heart Center of the University of Cologne), said, “There is currently no TAVR treatment for severe aortic regurgitation cleared by regulators. These patients do not typically develop calcification at the implant site, so other TAVR valves that rely on this narrowing to anchor their devices are at risk of migration. The JenaValve transcatheter valve may address this issue by securing the device with three novel locators that grasp the native valve leaflets. We have just begun study enrollment and treatment with this innovative transcatheter heart valve which has demonstrated low pressure gradients, no new pacemaker implantations and no paravalvular leak.”

“Our goal is to enable the treatment of patients with severe aortic regurgitation while avoiding many of the side-effects with off-label use of other TAVR devices in this patient population,” said JenaValve Chief Executive Officer Victoria Carr-Brendel, PhD. “We are excited to initiate this trial and look forward to expanding enrollment across multiple sites, building on this positive initial experience with our partners at the Heart Center of the University of Cologne.”

The Company expects to complete patient enrollment by the end of 2018 at clinical sites in Germany, The Netherlands, New Zealand and the United States. The Company anticipates CE Mark approval for treating patients with severe aortic regurgitation by the second half of 2019. The Company completed patient enrollment in a CE Mark study of the JenaValve Pericardial TAVR System for the percutaneous treatment of severe aortic stenosis and expects approval before the end of 2018.

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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