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JenaValve Technology Receives CE Mark for its Trilogy™ TAVI System for the Treatment of Aortic Regurgitation and Aortic Stenosis

IRVINE, Calif., May 25, 2021 (GLOBE NEWSWIRE) -- JenaValve Technology, Inc., developer, and manufacturer of differentiated transcatheter aortic valve implantation (TAVI) systems (also referred to as TAVR, or transcatheter aortic valve replacement) for the treatment of aortic valve disease, today announced that it has received CE Mark for its Trilogy™ Heart Valve System for the treatment of both aortic regurgitation (AR), also known as aortic insufficiency (AI), and aortic stenosis (AS).

The Trilogy Heart Valve System is the first transfemoral device of its kind to receive CE mark approval for the treatment of both severe symptomatic aortic regurgitation and aortic stenosis. Although TAVI devices have continued to advance in the marketplace, they are limited in their ability to treat aortic valve disease beyond aortic stenosis, which is marked by the high presence of calcium which is required to sufficiently anchor the valve in place. The Trilogy System, with its proprietary locator technology, does not rely on calcification to anchor the valve. Instead, the locators clip onto the patient's native anatomy to provide valve security. The valve's unique design also enables anatomical valve alignment, which facilitates future access to the coronary arteries and beneficial hemodynamics, both of which are significant clinical advantages for the treatment of aortic regurgitation and aortic stenosis.

"With the CE Mark, the Trilogy TAVI system becomes the first TAVI system in the world approved for the treatment of aortic regurgitation in high surgical risk patients. The Trilogy System now provides a clinically proven minimally invasive option for those in Europe suffering from the life-threatening effects of severe, symptomatic aortic regurgitation. We look forward to partnering with our key European sites and opinion leaders in the coming months to commercialize the Trilogy System for the treatment of both aortic regurgitation as well as aortic stenosis," said JenaValve CEO John Kilcoyne.

The JenaValve Trilogy System consists of a Transcatheter Heart Valve and Transfemoral Delivery System. The bioprosthesis comprises a self-expanding nitinol stent with a porcine pericardial tissue valve manufactured using state-of-the-art tissue processing techniques. The transfemoral delivery catheter is designed to deliver the bioprosthesis using a simple stepped approach to achieve anatomical positioning within the native valve. The System is available in three sizes, enabling treatment of a broad range of annular diameters.

"We now have a minimally invasive therapy option available that is uniquely designed for the challenging anatomical characteristics of the aortic regurgitation patient," said Univ-Prof. Stephan Baldus, MD, Director of the Heart Center Department of Cardiology at University Hospital Cologne and Co-Principal Investigator. "The Trilogy Valve System from JenaValve represents a significant improvement in our ability to confidently treat high surgical risk AR patients as this technology's features address the shortcomings of the existing TAVI devices in terms of valve stability, hemodynamics, and coronary access."

Severe high surgical risk aortic regurgitation (AR) is a condition that occurs when a patient's aortic valve does not close tightly, resulting in reverse blood flow from the aorta back into the left ventricle. The current treatment for high surgical risk patients who are not candidates for open heart surgery consists predominantly of medical management, and off-label TAVI.

"Alterations in the structure of valve complex in pure AR are distinct and present unique challenges due to absence of annular and leaflet calcification needed for device anchoring and stabilization during deployment," said Univ.-Prof. Hendrik Treede, MD, Director of the Clinic and Polyclinic for Cardiovascular Surgery at the University Hospital Mainz and Co-Principal Investigator. "JenaValve's locator technology provides a unique system of positioning and alignment with the native leaflets which I think provides my patients with several meaningful clinical advantages compared to current TAVI devices. With the Trilogy valve, we now have one aortic valve that meets the clinical demands of both aortic stenosis as well as aortic regurgitation. I can see how this valve may play a significant role in the field of transcatheter aortic valve implantation in the near future."

About JenaValve

JenaValve Technology, Inc., with locations in Irvine, California, Leeds, U.K. and Munich, Germany, develops and manufactures transcatheter aortic valve implantation (TAVI) systems to treat patients suffering from aortic valve disease.

JenaValve is backed by Bain Capital Life Sciences and Cormorant Asset Management as well as European and Asian investors, including Andera Partners (formerly Edmond de Rothschild Investment Partners), Gimv (Euronext: GIMB), Legend Capital, NeoMed Management, RMM, Valiance Life Sciences and VI Partners.

Additional information is available at www.jenavalve.com.

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