



## **FIRST RESULTS OF THE JUPITER REGISTRY ON LONG TERM PERFORMANCE AND SAFETY OF THE TRANSAPICAL JENAVALVE TAVI SYSTEM**

### ***30-Day Real World Data Shows Excellent Procedural Outcomes***

Wilmington, Delaware and Munich, Germany – May 22, 2013 – JenaValve Technology, Inc., a privately-held, venture-backed developer, manufacturer and marketer of transcatheter aortic valve implantation (TAVI) systems for the treatment of aortic valve disease, announced today its first interim results of the **J**enaValve **E**valuation of Long Term **P**erformance and Safety **I**n **P**atients with **S**evere **A**ortic Stenosis (JUPITER) Registry at EuroPCR in Paris. JUPITER is a post-market registry to evaluate five-year long term safety and effectiveness of the 2<sup>nd</sup> generation transapical JenaValve TAVI system in 180 elderly high-risk patients. The consecutive enrollment of the patients ensures that the patient population represents a real world clinical use of the device. All serious adverse events were source data verified. Major adverse events were adjudicated by an independent medical reviewer.

Since the first commercial implantation of TAVI systems in 2006, efforts of the manufacturers and physicians have been to further improve the handling of the devices and the clinical outcome. Device and procedural-related results including procedural success, stroke rates and paravalvular leakage are important drivers for patient safety.

With the 30-day results of the first half of the patients enrolled in the JUPITER registry, JenaValve demonstrated high procedural success rates and excellent clinical outcomes in a real world patient population with its transapical TAVI system. In 88 patients with a mean logistic EuroSCORE of 24.9 percent, the procedural success rate was 95.5 percent. Major adverse events such as major stroke (0.0 percent) or spontaneous myocardial infarction (1.3 percent) were very low and represent the safety of the JenaValve TAVI system. Excellent hemodynamics and very low paravalvular leakage (PVL) confirm the advantages of the system; 97.6 percent of the patients had a PVL  $\leq$  mild, severe PVL did not occur (0.0 percent).

The data was presented by Stephan Ensminger, MD, PhD, from the Heart and Diabetes Center NRW in Bad Oeynhausen, Germany, on behalf of the registry investigators. “The JUPITER registry confirms the excellent performance and safety of this 2<sup>nd</sup> generation TAVI system in a real world clinical use,” said Dr. Ensminger.

“The very good stroke and PVL data is especially impressive. With no PVL  $>$  mild and only 2.3 percent of moderate PVL, the JenaValve TAVI system shows one of the lowest PVL rates reported in a TAVI registry,” added Helmut J. Straubinger, CEO of JenaValve Technology.

### **About TAVI**

Transcatheter aortic valve implantation systems (TAVI) have already yielded nearly \$1 billion in revenues worldwide and the market is expected to grow to over \$3 billion in 2016<sup>1</sup>. Clinicians are now focused increasingly on TAVI technical and procedural refinements and advancements

found in second-generation products such as JenaValve's which address and resolve issues including ease of implantation, the need for post-procedure pacemaker implantation and post-implant paravalvular leakage.

### **About the JenaValve™ TAVI System**

The JenaValve is a true second-generation catheter-based aortic valve implantation system engineered and manufactured to the highest quality standards. The JenaValve transapical TAVI system is currently being sold in Europe. The Company's transfemoral TAVI system is expected to enter into clinical study later in 2013 and is anticipated to be available for sale in 2014.

- **The JenaValve prosthesis** consists of a natural aortic porcine root bioprosthesis fitted with an outer porcine pericardial patch, a so-called skirt, before being sewn onto a Nitinol self-expanding stent. The high-quality bioprosthesis is durable, ensuring long-term aortic valve function.
- **JenaValve's unique "3-feeler element"** allows the clinician to accurately position the prosthesis in the anatomically correct position during implantation thus ensuring a precise sub-coronary alignment within the patient's native valve.
- **JenaClip™ anchoring and clipping mechanism** allows the patient's native valve leaflets to be clipped to the valve enabling the JenaValve to be firmly anchored in the correct anatomical position and provide active fixation and resistance to migration.
- **The JenaValve implantation** is conducted on the beating heart. Hemodynamic flow is maintained without cardiac arrest and rapid pacing is not required during the procedure. The low profile of the stent prosthesis ensures open flow to the coronaries after the implantation. The JenaValve is available in three sizes, 23mm, 25mm and 27mm, covering aortic valve annuli from 21mm to 27mm.
- **JenaValve is retrievable and repositionable** thereby contributing to a successful procedure and confidence of the clinician.

### **About JenaValve Technology**

JenaValve Technology, Inc., domiciled in Delaware, USA with operations in Munich, Germany, develops, manufactures and markets aortic valve systems to treat patients suffering from aortic valve disease. The company's products are CE marked and its transapical aortic valve system is currently marketed in Europe with over 400 implantations to date. JenaValve is backed by world-class U.S. and European investors: Atlas Venture, Edmond de Rothschild Investment Partners, NeoMed Management, VI Partners, Sunstone Capital and GIMV. Additional information is available at [www.jenavalve.com](http://www.jenavalve.com)

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