



## **PRIMARY ENDPOINT DATA PRESENTED ON PERFORMANCE AND SAFETY OF THE JENAVALVE TAVI SYSTEM**

### ***Data on Real-World Patient Population Shows Excellent Clinical Results; New Cathlete Plus™ Delivery System Provides Improved Ease-of-Use, Outcomes***

Wilmington, Delaware and Munich, Germany – May 21, 2014 – 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, today announced the results of the JenaValve Evaluation of Long Term Performance and Safety In Patients with Severe Aortic Stenosis (JUPITER) Registry at EuroPCR in Paris. JUPITER is a post-market registry designed to evaluate acute, 30-day and long-term safety and effectiveness of the 2<sup>nd</sup> generation transapical JenaValve TAVI system in elderly high-risk patients. All major VARC I events were adjudicated by an independent medical reviewer with 100% SAE event monitoring.

“The JUPITER registry is based on a high-risk patient population with severe degenerative aortic valve disease,” said Prof. Olaf Wendler, Consultant Cardiothoracic Surgeon at King’s College Hospital London and principal investigator for the registry. “The positive outcomes and low adverse event rates, confirm the benefit of treating patients suffering from aortic stenosis with the JenaValve TAVI system.”

In the 30-day results, JenaValve demonstrated good procedural success rates and excellent clinical outcomes in a real world patient population. In 180 patients with a mean logistic EuroSCORE of 22.3 percent, the procedural success rate was 95 percent. Major adverse events such as major stroke (1.1 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; 99.4 percent of the patients were discharged with PVL that ranged from non-existent to mild, severe PVL did not occur in any of the discharged patients.

“The low PVL rates are particularly promising as post-implantation leakage around the valve is a common concern and a dangerous side effect often seen in patients with severe calcification of the valve or valve leaflets. JenaValve’s technology enables precise anatomically correct positioning and more secure attachment to even highly calcified anatomies, resulting in one of the lowest PVL rates seen in other published registry data,” Prof. Wendler added.

Prof. Dr. Hendrik Treede, MD, Senior Consultant at the University Heart Center in Hamburg and co-investigator for the JUPITER registry, stated, “More than 25% of the patients included in the registry have been treated using a new proprietary delivery system called Cathlete Plus™. Cathlete Plus received CE Mark in September 2013 and we have been one of the first centers using it. The functional improvements compared to the Cathlete delivery system were obvious already in the first case: it’s intuitive and reliable design has improved the ease of use and gives you control over delivery and placement of the prosthesis. The registry confirms now that these improvements also result in outcomes even better than the legacy delivery system. The JUPITER data shows a procedural success of almost 98% and an all-cause mortality of 8,5%.”

Helmut J. Straubinger, CEO of JenaValve Technology said, “We are very encouraged by the excellent patient outcomes and positive physician feedback related to the new Cathlete Plus delivery system. The JUPITER Registry data continue to demonstrate that the unique advantages of the JenaValve system result in beneficial clinical outcomes for patients suffering from aortic valve calcification.”

## 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 and other markets worldwide. The Company’s transfemoral TAVI system entered into a first-in-man clinical study at the end of 2013 and is anticipated to be commercially available for sale in 2015.

- **The transapical 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 to achieve the correct implantation height and commissural alignment within the patient’s native valve.
- **JenaClip™ anchoring and clamping mechanism** allows the prosthesis to be clamped onto the patient’s native valve leaflets 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 and the open cell design of the stent prosthesis ensure 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., a U.S. corporation with primary operations in Munich, Germany, develops, manufactures and markets transcatheter aortic valve implantation (TAVI) systems to treat patients suffering from aortic valve disease. JenaValve was founded in 2006 by cardiologists and inventors Prof. Hans R. Figulla, M.D. and Prof. Markus Ferrari, M.D.. The Company’s transapical TAVI system is CE marked and currently marketed in Europe and other

markets worldwide. JenaValve is backed by world-class U.S., European and Asian investors. Additional information is available at [www.jenavalve.com](http://www.jenavalve.com)

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- 1) Goldman Sachs Global Investment Research