



JENAVALVE ANNOUNCES FIRST IMPLANTATION OF TRANSAPICAL TAVI SYSTEM IN SWEDEN

Company Continues to Expand Commercialization of Second-Generation Device in Europe

Wilmington, Delaware and Munich, Germany – June 4th, 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, announced today that it has successfully completed the first implantation of its second-generation transapical JenaValve TAVI system in Sweden.

The implantation was performed by cardiac surgeon Dr. Vilyam Melki from Uppsala University Hospital, Uppsala, Sweden. Prof. Hans R. Figulla, M.D., Director of the Clinic for Internal Medicine and Cardiology in Jena, Germany, served as proctor to support the implantation.

“We treated one patient suffering from aortic valve stenosis that was declined for open heart surgery due to comorbidity. The patient had a severely calcified valve with an unsymmetrical calcium distribution”, Dr. Melki declared. “We have chosen the transapical JenaValve TAVI System because we think that its unique features are beneficial for this kind of patients. The JenaValve TAVI System consists of a self-expanding Nitinol stent with three so-called feelers that “guide” the prosthesis into the anatomically correct position. Furthermore, the prosthesis is fixed onto the native valve leaflets with a clipping mechanism, similar to a paper-clip. The advantage of this mechanism is that it works independently of the calcification level of the native valve and does not put stress on annulus and aorta and thus reduces the risk for any dissection or calcium migration.”

Dr. Melki added: “The first case showed that the JenaValve was the right decision: the prosthesis was introduced and delivered properly and the clinical outcome proves the concept. The patient had well improved haemodynamics, no paravalvular leakage (PVL) and no signs of coronary obstruction, AV-block or neurological changes”

The first JenaValve implantation in Sweden once more confirms the company’s strategy to further expand its business across Europe, Helmut J. Straubinger, CEO of JenaValve Technology, stated.

“We see a continuous expansion of our unique TAVI system because of its features and the resulting patient benefits. We have proven the advantages in a wide range of treatments worldwide, underlined by recently published clinical data of our post-market registry JUPITER. We are really looking forward to offer our technology to physicians and patients in Sweden.”

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 2016¹. 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. The Company's transfemoral TAVI system is currently under clinical investigation and is anticipated to be commercially available for sale in 2015. JenaValve is backed by world-class U.S., European and Asian investors. Additional information is available at www.jenavalve.com.

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