



JENAVALVE TAVI SYSTEM RECEIVES EXTENDED CE MARK APPROVAL FOR TREATMENT OF AORTIC INSUFFICIENCY

Only TAVI System with Indications to treat Aortic Stenosis and Aortic Insufficiency

Wilmington, Delaware and Munich, Germany – September 16th, 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 it has received CE (Conformité Européenne) Mark approval from European regulators for its transapical TAVI system for the treatment of aortic insufficiency (AI), a condition also known as aortic regurgitation in which the native aortic valve does not close properly, allowing blood to leak back into the left ventricle of the heart.

The JenaValve is now the only TAVI device worldwide approved for the treatment of high-risk or inoperable patients suffering from severe aortic insufficiency. The CE Mark expansion, which is an addition to JenaValve's initial September 2011 CE Mark approval for the treatment of stenosed and calcified aortic valve diseases, enables JenaValve to market its product for AI to physicians and their patients throughout all countries recognizing the CE Mark. The JenaValve is now approved for the entire range of aortic valve disease - from severely calcified to not calcified at all.

JenaValve CEO Helmut J. Straubinger said, “The granting of a CE Mark expansion to cover the clinical indication of aortic insufficiency is testament to the unique design of our valve and will provide a new option for thousands of patients; more than 23% of all patients with native aortic valve diseases suffer from AI. Today, open-heart valve replacement surgery is the standard procedure for AI patients, high-risk patients or inoperable patients are treated conservatively with drugs. According to published clinical data, the yearly mortality rate of these conservatively treated patients is approximately 25%. For these patients the JenaValve now provides a beneficial alternative treatment opportunity. This new approval means our transapical TAVI system, compared to all other competitors, can now treat the broadest range of patients.”

JenaValve's competitive advantage for AI is attributable to its patented clip-mechanism that allows for “active fixation” on the diseased valve leaflets and requires no calcification of the native valve to be implanted and effective. The JenaValve TAVI system is clipped and fixed on the native valve leaflets in a manner similar to a paper clip. Other competing TAVI products are not suitable for AI because they require a certain amount of calcification in order to properly position and secure their valve prosthesis. Without calcification there is significant risk that these other devices will migrate into the aortic arch causing risk to the patient. Clinical studies performed with competitor devices in patients with pure AI revealed unsatisfying results with a high number of residual paravalvular leaks requiring second interventions.¹

Prof. Hendrik Treede, M.D., Director Minimally Invasive Cardiac Surgery at the University Heart Center Hamburg, said, “Severe aortic regurgitation is an indication for surgical aortic valve repair or replacement in the majority of patients. Nevertheless there is a need for interventional catheter based aortic valve implantation in patients at high surgical risk or with

contraindications for surgery. First generation TAVI devices require substantial oversizing in non-calcified annuli carrying the risk of paravalvular leakage, valve migration or further annulus dilatation. The JenaValve TAVI system has proven safety and efficacy in catheter-based treatment of pure aortic regurgitation in sufficient numbers of patients. The unique clip-mechanism fixes the native leaflets to the stent thereby achieving anatomically correct implantation and full coverage of the native annulus without the need for extensive oversizing and without paravalvular leak. Transapical JenaValve implantation has become the treatment of choice for patients with pure or predominant aortic regurgitation at high risk for surgery at the University Heart Center Hamburg.”

About TAVI

Transcatheter aortic valve implantation (TAVI) systems produce in excess of \$1 billion in annual revenues worldwide and the market is expected to grow to over \$3 billion in 2016². Clinicians are now increasingly focused on TAVI technical and procedural refinements and advancements found in next-generation products such as JenaValve’s that 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 around the world. The Company’s transfemoral TAVI system is expected to enter into clinical study in late 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 onto 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., 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 aortic valve 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: Atlas Venture, Edmond de Rothschild Investment Partners, NeoMed Management, VI Partners, Sunstone Capital, GIMV, Legend Capital and Omega Funds. Additional information is available at www.jenavalve.com

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- 2) Goldman Sachs Global Investment Research