



FIERCEMEDICALDEVICES NAMES JENAVALVE ONE OF ‘FIERCE 15’ TOP MEDICAL DEVICE AND DIAGNOSTIC COMPANIES OF 2013

Unique Technology, Design Represent Competitive Advantage

Wilmington, Delaware and Munich, Germany – October 15, 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 that it has been named to the *FierceMedicalDevices* “Fierce 15” list, designating it as one of the most promising private companies in the medical device industry in 2013. JenaValve was chosen as one of the Fierce 15 based, in part, on the innovation and promise of the JenaValve TAVI System.

“JenaValve and the other Fierce 15 companies we chose represent some of the best and brightest in the device and diagnostic industries today,” *FierceMedicalDevices* Editor Damian Garde said. “They’ll be producing big things in the months ahead.”

The global market for TAVI systems is expected to grow to more than \$3 billion in 2016.

Last month, the JenaValve TAVI System was granted 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 approved for the entire range of aortic valve disease - from severely calcified to not calcified at all – and is the only TAVI device worldwide approved for the treatment of high-risk or inoperable patients suffering from severe aortic insufficiency.

“We are encouraged that medical device editors in the US are recognizing the value of the JenaValve TAVI System, and even more important, the large and growing patient population that can now benefit from our proprietary devices,” said JenaValve CEO Helmut J. Straubinger. “Our unique technology and the design of our valve are our competitive advantages. We are looking forward to expanding our commercial footprint in new geographies around the world.”

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 more than \$3 billion in 2016¹. 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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