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JenaValve™ reports significant clinical milestone: first-ever successful transcatheter implantation of a 27mm transapical aortic valve prosthesis

“With the availability of a transapical aortic prosthesis for sizes up to 27mm, the market for TAVI patients will be significantly expanded, providing life-saving therapy to patients previously left untreated.”

**Hans-Reiner Figulla, M.D.
Co-Founder, JenaValve; JenaValve SAB Head;
Professor and Director, Cardiology Clinic,
Friedrich Schiller University, Jena, Germany**

WILMINGTON, Del., USA, and MUNICH, Germany, Jan. 18, 2011 — JenaValve™ Technology, Inc., a medical device company specializing in developing transcatheter aortic valve implantation (TAVI) systems, announced today a significant clinical milestone: the first-ever successful transcatheter implantation of a 27mm transapical aortic valve prosthesis.

The milestone procedure was performed by cardiac surgeon **Dr. Hendrik Treede** at the [University Heart Center Hamburg](#) (www.uhz.de <<http://www.uhz.de>>). The case was performed on a patient included in JenaValve’s ongoing pivotal CE mark trial.

“The procedure was very straightforward and uneventful,” said Dr. Treede. “Our experience with the JenaValve system is that it provides a stable platform for cardiac surgeons to carefully position and release the prosthesis. JenaValve’s technology represents a noteworthy clinical and technical achievement allowing us to expand the use of life-enhancing TAVI procedures.”

“The significance of this clinical milestone cannot be overstated,” said **Hans-Reiner Figulla, M.D.**, Co-Founder and SAB Head of JenaValve; and Professor and Director, Cardiology Clinic, Friedrich Schiller University, Jena, Germany. “Existing, CE-certified transapical TAVI products currently available on the market are indicated for annular sizes up to 25mm. With the availability of a transapical aortic prosthesis for sizes up to 27mm, the market for TAVI patients will be significantly expanded, providing life-saving therapy to patients previously left untreated,” Professor Figulla said.

“Indeed, more than 30% of all patients with symptomatic severe aortic stenosis (SAS) are not referred or are contraindicated from current surgical valve replacement,” added **Helmut J. Straubinger**, CEO of JenaValve Technology.

JenaValve is in the midst of a multicenter CE-mark pivotal study to evaluate the safety and effectiveness of its transapical TAVI system. The primary endpoint of the trial is the 30-day mortality rate; secondary endpoints are procedural success, valve performance and safety.

JenaValve has designed a transapical (TA) platform for heart surgeons. Its transfemoral (TF) platform for cardiologists is in development. Each of these systems is comprised of three state-of-the-art components: (1) a catheter delivery system; (2) a unique, self-expanding nitinol stent; and (3) a heart valve—the transapical prosthesis uses a porcine root valve, while the transfemoral prosthesis is a pericardial tissue construct, allowing for a small catheter diameter. JenaValve expects to enter the European market with its transapical TAVI system in 2011.

Aortic stenosis, the most prevalent heart valve disease in Western countries, is increasing steadily with an aging population. The decision to surgically replace a diseased aortic valve is problematic in elderly patients due to associated high mortality and morbidity risks. In fact, elderly patients with severe aortic disease symptoms are not often considered candidates for surgery. JenaValve's advanced TAVI systems are designed for this type of patient. JenaValve's **second-generation TAVI systems** also are designed to enable correct positioning, re-positioning and retrievability for patient safety, and ease-of-handling for physicians. The company's TAVI systems are designed to reduce the long learning curve associated with TAVI devices now used by physicians.

About JenaValve Technology

JenaValve Technology is a medical device company focused on developing transcatheter valve implantation systems to treat patients suffering from aortic valve disease. The company has transcatheter aortic valve implantation (TAVI) systems for both **transapical** and **transfemoral** approaches to address the needs of the cardiac surgeon and cardiologist, respectively.

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