



Press Release

JenaValve Technology Reports Nine Successful Human Implantations of its Transapical TAVI System

Completes First-in-Man TAVI Procedures

DELAWARE, USA and MUNICH, Germany, May 25, 2010 — JenaValve™ Technology, Inc., a medical device company specializing in developing transcatheter valve implantation systems, today announced that it has completed First-in-Man (FIM) procedures for its transapical transcatheter aortic valve implantation (TAVI) system. The procedures and implantations were successfully performed in nine patients at the Heart Center, Leipzig, Germany.

Commenting on the announcement, JenaValve's CEO Helmut J. Straubinger said, "I am very pleased that our interdisciplinary team has achieved FIM for our transapical system. Our product design and development team deserves our highest recognition for having produced a safe, next-generation system – German precision engineering at its best."

The goals of the study were to assess (1) the deliverability of the prosthesis, (2) repositioning and retrievability, and (3) new valve function in elderly, high-risk patients with severe aortic stenosis and co-morbidities. Thirty-day mortality and procedural success were the primary endpoints of the FIM trial.

Prof. Dr. med. Friedrich-Wilhelm Mohr, Director of the Clinic for Cardiac Surgery, Heart Center Leipzig and Principal Investigator affirmed, "The JenaValve FIM is an exciting milestone in the development of TAVI systems. As long-term data are gathered and the next-generation technology is available, we expect that the transcatheter approach will replace invasive surgical treatment in many selective cases and become an alternative for high-risk patients that promises faster recovery and enhanced quality of life."

Prof. Dr. med. Hans-Reiner Figulla, Director of the Cardiology Clinic, Friedrich Schiller University Jena, and Founder and Head of the JenaValve Scientific Board, added, “The JenaValve FIM is an admirable medical and technical achievement, demonstrating that the company’s prosthesis can be used for life-enhancing TAVI procedures. We are elated that all patients in whom the JenaValve prosthesis was implanted passed the 30-day follow-up visit. I am especially pleased that all prostheses were easily, correctly and precisely placed in patient annuli and that excellent hemodynamics confirmed the function of the JenaValve prostheses without pacemaker need.”

Patient characteristics:

- Total enrollment: 12 patients; 9 successfully treated; 1 procedural failure (Type A dissection), 2 abortions due to unsuitable anatomy; following a catheter design modification continuous procedural success
- Mean age: 86.3 years
- Gender: all female
- Logistic EuroScore: 22.4%
- NYHA classification III for all patients
- Annuli ranged between 21,0 and 22,9 mm

JenaValve transapical FIM results:

- Implantation in nine patients was a procedural success
- All patients passed the 30-day survival endpoint
- Precise orientation, correct positioning and placement of the prosthesis
- Hemodynamic results: mean gradient 9 mmHg; peak gradient 15 mmHg after 30 days
- No device migration or coronary obstruction
- No intraoperative death
- No myocardial infarction, stroke or death with 30 days
- No post-operative conductivity impairment requiring a permanent pacemaker
- Implantation time was consecutively reduced from seven to three minutes

Summary: The JenaValve system design enables the physician to advance, rotate, reposition or retract the unique, patent-protected feelers as necessary, leading to correct and precise placement of the prosthesis.

Management and product photos are available on request

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.

The JenaValve next-generation TAVI system provides three fundamental, patented, design features:

- the unique positioning feelers
- the JenaClip™ anchoring mechanism and
- the low profile JenaValve prosthesis

These are the elemental differentiators with which the TAVI implantation can be accomplished more precisely and more easily than with other available TAVI systems.

JenaValve Technology GmbH is headquartered in Munich, Germany; its holding company is JenaValve Technology, Inc., Delaware, USA. Additional company information is available at www.jenavalve.de.

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