



Press release

FOR IMMEDIATE RELEASE

US Media/Investor Contact:

Ronald Trahan, APR, Ronald Trahan Associates, +1-508-359-4005, x108

JenaValve is first in receiving CE certification for a true second generation transapical TAVI system

Results of the pivotal CE-mark trial of the JenaValve transapical TAVI system are being presented for the first time, on October 3rd, at the 25th Annual Meeting of the European Association for Cardio-Thoracic Surgery (EACTS) in Lisbon

MUNICH, Germany, Sept. 30, 2011 — JenaValve Technology GmbH, a German medical device company specializing in the development of transcatheter heart valve implantation systems, announced today that the Company has received CE mark approval for its second-generation transapical TAVI system. This system is used to treat severe aortic valve stenosis in elderly high-risk patients, especially in patients for whom conventional open-heart surgery is not an option.

"After an exciting and suspenseful development period, we are now able to commercially release our second generation TAVI system, firstly onto the European market," said Helmut Straubinger, President and CEO of JenaValve Technology. "Our transapical TAVI system is designed to offer patients and teams of cardiac surgeons and cardiologists a significant advantage over currently available transcatheter aortic valve implantation systems."

The pivotal CE-marking study is a prospective, multicenter, uncontrolled clinical trial comprising 73 patients with severe symptomatic aortic valve stenosis, which was held at seven German study sites between October 2010 and July 2011. The primary endpoint of the trial was the 30-day mortality rate. The secondary

endpoints were the rate of successful implantation, as well as further parameters for performance and safety of the prosthetic heart valve. The first results of the study's primary endpoint are being presented at the preeminent EACTS scientific meeting on October 3, 2011, in Lisbon.

In his podium presentation, cardiac surgeon Dr. Hendrik Treede from the University Heart Center in Hamburg will present the study data ("Safety and efficacy outcomes from the multicenter CE-mark study using the JenaValve™ second-generation transcatheter aortic valve implantation [TAVI] system"). The presentation will take place at 11:45 in Auditorium 1 at the Lisbon Congress Center.

Prof. Dr. Friedrich-Wilhelm Mohr, Medical Director of the Department of Cardiac Surgery at the University of Leipzig Heart Center, is the Principal Investigator of the multicenter study. "The study appears to be progressing very promisingly, and the 30-day trial data support the safety and efficacy of the JenaValve system. Now patients have access to a new generation system for transapical TAVI treatment. The JenaValve design allows the cardiac surgeon and cardiologist to achieve precise positioning and allows repositioning of the heart valve prosthesis with its unique, patented positioning feelers. It is with these key features that the system distinguishes itself from its competitors," said Prof. Mohr.

Product description:

The transapical TAVI system consists of both the Cathlete delivery system and The JenaValve heart valve prosthesis. The product is available in three sizes and covers aortic annulus diameters from 21 to 27mm.

Information on the JenaValve TAVI system

JenaValve has focused its product development on fundamental, patented design features:

- The JenaValve prosthesis with a low profile
- The unique positioning feelers
- The JenaClip anchoring mechanism
- The ability to reposition the prosthesis

About JenaValve Technology

JenaValve Technology is a medical device company focused on developing transcatheter-delivered aortic valve systems to treat patients suffering from aortic valve disease. The company develops replacement aortic valve systems for both transapical and transfemoral approaches (TAVI) to address the needs of cardiac surgeons and cardiologists. JenaValve is backed by its committed investors: Atlas Venture, Edmond de Rothschild Investment Partners, NeoMed Management, VI Partners, Sunstone Capital, Gimv. In Europe, JenaValve Technology GmbH is headquartered in Munich, Germany; its holding company is JenaValve Technology, Inc., Delaware, USA. Additional information is available at www.jenavalve.de.

JenaValve and JenaClip are trademarks of JenaValve Technology GmbH. JenaValve products are protected by pending and granted patents as well as by design and utility model rights.

Press contact:

Daniela Daiker
JenaValve Technology GmbH
Guerickestraße 25
80805 Munich
daiker@jenavalve.de
+49-89-552790828

Printable photos of products and the management team are available on request.