



Symetis ACURATE TF™ FIM Trial Completed

- All sizes (21mm-27mm) used during FIM study
- CE-mark study currently enrolling patients
- Data update at TCT2012

Ecublens, Switzerland, October 22, 2012 – Symetis Inc., a private Swiss company developing new transcatheter aortic valve implantation (TAVI) systems, announced during the PCR London Valves meeting that it finished enrollment (n=20) in its First-In-Man (FIM) trial of the transfemoral aortic valve replacement device, the ACURATE TF™ Aortic Bioprosthesis and Delivery System.

ACURATE TF™ FIM Study:

The FIM trial was conducted at four different centers in Brazil and Germany. The device was implanted with a procedure success rate of 95.0% (n=19) as one patient received a valve-in-valve procedure due to too low placement of the bioprosthesis in the LVOT. At 30 days follow-up, the mean gradient is 7.1 ± 3.1 mmHg with a mean EOA of 1.8 ± 0.4 cm². Paravalvular leak rate is very low with 94.5% of patients exhibiting none to mild leak (<+2). There is no occurrence of mortality at 30 days and one stroke was reported in the valve-in-valve patient. The Study PI, Prof. Helge Moellmann of the Kerckhoff Clinic in Bad Nauheim, Germany, stated: "this 2nd generation TF system has exhibited impressive results in its FIM trial already mirroring the ease of use of its commercially available transapical system, the ACURATE TA™".

ACURATE TF™ Transfemoral Aortic Bioprosthesis

Based upon the same self-seating, self-sealing architecture and stepped deployment concept of its already marketed transapical sister product, the ACURATE TA™ Aortic Bioprosthesis, the ACURATE TF™ is composed of a porcine pericardial tissue valve sutured within a self-expanding nitinol stent covered by a pericardial skirt on the interior and exterior of the device. The bioprosthesis is available in three sizes (S, M, & L) to treat aortic annulus diameters from 21mm to 27mm and its Delivery System boasts an 18F outer diameter delivery catheter.

The CE-mark study has been initiated late September 2012 and the ACURATE TF™ system should receive a CE Mark mid 2013.

Data update on ACURATE TF™ FIM will be presented at TCT2012 (Miami) on Wednesday Oct. 24th at 3:30pm during the *Next generation Trans-catheter Aortic Valve Therapies* Spotlight session.

About Symetis

Symetis Inc. is a private Swiss company developing innovative, minimally invasive heart valve replacement solutions (www.symetis.com). The company's products, ACURATE TA™ and ACURATE TF™, are based on proprietary geometry and delivery technologies and are well positioned to target the estimated \$2 billion TAVI market. Based in Lausanne, the company is financed by leading European venture capital firms, including Truffle Capital, Novartis Venture Fund, Wellington Partners, Aravis Venture, Vinci Capital, Banexi Ventures, Endeavour Vision, NBGI Ventures and BiomedInvest.

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