



Symetis announces successful, first time implantation of its ACURATE TA™ and ACURATE TF™ TAVI systems in Japan

- **Procedures performed at Osaka University Hospital**
- **Four patients successfully treated in initial feasibility study**
- **Results to support PMDA filing**

Ecublens, Switzerland, August 12, 2013 – Symetis Inc., a privately-owned Swiss company focused on transcatheter aortic valve implantation (TAVI) systems, announced that its ACURATE TA™ and ACURATE TF™ TAVI systems were used to successfully treat patients at the Department of Cardiovascular Surgery of the Osaka University Graduate School of Medicine. These procedures were performed as part of a feasibility study being conducted under the leadership of Professor Yoshiki Sawa.

The four patients were treated by Professor Toru Kuratani, with two patients receiving a transapical ACURATE TA™ valve and two patients receiving a transfemoral ACURATE TF™ valve. Immediate post-operative results demonstrated excellent outcomes, with all valves presenting zero or trace paravalvular leak, single-digit gradient and no complications.

Professor Y. Sawa, who will be the principal investigator of the upcoming PMDA study stated: “This is the first time that a second generation TAVI was implanted in Japan and we are proud to lead this clinical effort to bring the ACURATE™ TAVI systems to our patient population. These cases also marked our 100th TAVI implantation at Osaka University Hospital.”

Professor T. Kuratani commented on the ease of use of the Symetis products: “The uncomplicated, step-by-step delivery process for both the ACURATE TA™ and ACURATE TF™ provides the implanter with full control until final delivery. The positioning is intuitive and the absence of paravalvular leak is impressive”.

PMDA Filing:

The implantations at Osaka University Hospital are part of a feasibility study to support the filing with the Japanese Pharmaceutical and Device Agency (PMDA) for a multi-center pre-market approval study. Laura Brenton, VP Clinical and Regulatory Affairs at Symetis explained: “We will use these feasibility data and our European CE mark study data to determine, with PMDA, the most efficient path to bring these products to the Japanese market.”

According to GBI Research, the Japanese TAVI market is expected to approach 4,000 annual TAVI procedures by 2017, with both transapical and transfemoral systems being used by physicians. “With some of the highest standards in cardiac surgery and interventional cardiology, and proportionally the largest elderly population worldwide, Japan is prone to embrace TAVI and represents an exciting opportunity to expand our clinical and commercial activity beyond Europe,” concluded Jacques Essinger, Symetis’ Chief Executive Officer.

About the ACURATE TA™ & ACURATE TF™

The commercially available, self-expanding ACURATE TA™ has a unique and intelligent design featuring a two-step single operator deployment technique. The most important differentiator is the “self-seating and self-sealing” architecture combined with outstanding ease-of-use throughout the procedure. This supports optimal positioning and sealing of the valve and therefore, delivers reduced paravalvular leak and improved outcomes. The ACURATE TA™ is available in three sizes (S, M, L) to treat patients with aortic annulus diameters from 21mm to 27mm.

ACURATE TF™, Symetis' transfemoral TAVI system, is based on the same self-seating, self-sealing design and stepped deployment concept of ACURATE TA™ and is currently under clinical investigation to obtain CE mark by end 2013. 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. ACURATE TF™ will be available in four sizes (XS, S, M, L) and its Delivery System boasts an 18F outer diameter.

For more information on ACURATE TA™ and ACURATE TF™, please see www.pconline.com/redirect/2013-EuroPCR-Symetis/

About Symetis

Symetis Inc. is a privately-owned 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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