

## **Symetis' ACURATE TA™ confirms superior results Post-Market Registry Data Confirm a High Procedure Success Rate, Superior Safety Profile and Minimal PV Leak in Commercial Use**

- **Discharge/30-day follow-up data presented in the German Cardiac Society meeting in Mannheim**
- **The 17 center, 250 patient registry represents real-life use of the ACURATE TA™ Transapical Aortic Bioprosthesis in clinical practice**
- **Low complication rates set a new standard for optimal transcatheter aortic valve implantation (TAVI)**

**Ecublens, Switzerland, April 3rd, 2013** – Symetis Inc., a private Swiss company, developing 2<sup>nd</sup> generation transcatheter aortic valve implantation (TAVI) systems, presented today discharge and 30-day follow-up data from the **Symetis ACURATE TA™ Valve Implantation (SAVI) Registry** during the 79<sup>th</sup> Annual German Cardiac Society Meeting. SAVI is a post-market registry of the first 250 patients treated with the ACURATE TA™ that was granted CE mark in September 2011. The included patients were implanted at 17 centers in Germany, Switzerland, Argentina and Italy and reflect real-life clinical use of this 2<sup>nd</sup> generation TAVI device

Current efforts in TAVI are directed toward simplifying positioning and deployment, reducing procedure-related complications, including major cardiovascular events and paravalvular regurgitation. The results of this post-market registry of the ACURATE TA™ reveal a high procedure success rate (98.0%) confirming the system's unparalleled ease-of-use and nearly non-existent learning curve. Additionally, a very good safety profile and minimal PV leak rate as had already been observed in pre-market clinical trials of the device, were also reported. The SAVI Registry shows a 30-day all-cause mortality rate of 6.8% - one of the lowest rates reported in registries of other transcatheter aortic valves (1-5). Hemodynamics and functional class improved solidly after the ACURATE TA™ implant procedure. Serious adverse events such as stroke (2.8%), myocardial infarction (0.8%), and new permanent pacemaker implantation (7.2%) rates were also very low. Furthermore, the ACURATE TA™ exhibits the lowest PVL reported in a TAVI registry with only 2.7% of patients with a PV leak ≥ Grade 2 at follow-up.

Prof. Thomas Walther MD, Kerckhoff Klinik, Bad Nauheim and Principal Investigator of the study, commented: "Patient safety is my highest priority. I am impressed by these real-world results and the consistent safety profile of ACURATE TA™."

Laura Brenton, VP Clinical & Regulatory Affairs at Symetis, added: "The ACURATE TA™ has proven to be the most user-friendly and patient-effective transapical TAVI today on the market. Our TA R&D pipeline will further raise this new standard and expand the TA indication. I also wish to thank all the investigators for their active support."

### **About the ACURATE TA™**

The 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" design combined with outstanding ease-of-use throughout the procedure. The self-positioning features ensure optimal fit of the bioprosthesis the first time. This results in less risk for incorrect placement and promotes sealing at the correct position for minimal leak. The ACURATE TA™ is available in three sizes (S, M, L) to treat patients with aortic annulus diameters from 21mm to 27mm.

### **Future developments**

Based upon the same self-seating, self-sealing design and stepped deployment concept, Symetis' transfemoral TAVI system, ACURATE TF™, has begun its CE Mark trial, which is expected to close enrolment in June and lead to market approval in 2013. 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 ACURATE TF™ is also available in three sizes (S, M, L) and its Delivery System boasts an 18F outer diameter.

### **About Symetis**

Symetis Inc. is a private Swiss company developing innovative, minimally invasive heart valve replacement solutions ([www.symetis.com](http://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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