Symetis' ACURATE TA™ Aortic Bioprosthesis Receives CE Mark Certification on Sept. 30th 2011

- **Largest 2nd generation TAVI system clinical experience**
- **Mid-term FIM study results to be presented at EACTS 2011 on October 3 in Lisbon**

Lausanne, Switzerland, October 2, 2011 – Symetis SA, a private Swiss company developing new transcatheter aortic valve implantation (TAVI) systems, announced during the Techno-College at the EACTS (European Association for Cardio-Thoracic Surgery) meeting in Lisbon that it received CE Mark approval for its ACURATE TA™ transapical TAVI system. The approval of this 2nd generation TAVI device, used to treat elderly patients with severe aortic stenosis (AS) for whom open surgical repair is considered to be high risk, opens the company to a market estimated to exceed $2 billion by 2014.

CE Mark approval:
Symetis performed two clinical trials of the ACURATE TA™ in Germany: a FIM trial (n=40) and a Pilot study (n=50). The CE Mark was granted by the National Standards Authority of Ireland (NSAI, www.nsai.ie) using a composite of patients from both studies, including 65 patients followed at 30 days, 30 patients at 6 months and 10 patients at 1 year. The completion of enrolment in both studies translates to Symetis ACURATE TA™ having the largest clinical experience to date of any 2nd Generation TAVI device in clinical trials or approved for market. In addition, this dataset establishes a new standard for the approval of future 2nd generation TAVI systems.

Clinical experience:
Both studies were single-arm, prospective, multicenter trials that enrolled high-risk patients with severe AS. The combined patient cohort consists of 90 patients enrolled at six investigation centers in Germany between November 2009 and July 2011. The primary endpoint of both studies is 30-day mortality. Primary endpoints included procedure success (95%) and safety/performance data collected at 30 days, 6 months and 1 year. The secondary endpoints are MACCE, as well as ECHO parameters evaluating performance of the ACURATE TA™. Dr. Joerg Kempfert will present the midterm results of the FIM trial at the 25th EACTS Annual Meeting on October 3, 2011 in Lisbon.

Commercial launch:
The commercial launch of the ACURATE TA™ is taking place during the EACTS meeting, with an initial focus on Europe. In parallel, a 150-patient, 15-center Pivotal trial will be conducted to support the company's US strategy. Also, a post-market surveillance study, SAVI (Symetis Aortic Valve Implantation Registry), will begin with implantation of commercial products.

Prof. Thomas Walther, Study PI, commented: "The Symetis ACURATE TA™ and Delivery System received CE Mark approval after proving safety, efficacy and ease of use in the FIM and Pilot studies. Patients had good functional outcome with low level of paravalvular leak, which may be a good prognostic factor for long-term favorable outcomes. The CE Mark is an acknowledgment of the solid development work delivered by the company's team of engineers."

Laura Brenton, VP Clinical / Regulatory Affairs, said: "Investigators using the ACURATE TA™ in both the FIM and Pilot studies acknowledged its ease of use. The device's simple positioning and 2-step deployment, accompanied by tactile feedback facilitating release in the

correct annular position, were considered by all physicians to be the easiest delivery of a transcatheter valve to date. The system's simplicity translates into a shorter learning curve compared to other TAVI systems currently on the market or still in clinical trials. Furthermore, the robust dataset of 90 implanted patients also allows for comparison of the ACURATE TA™ to published statistics from 1st generation TAVI devices, suggesting comparable or improved initial outcomes."

Jacques R. Essinger, CEO of Symetis, added: "This is a major milestone in the development of our company. While we will now expand our clinical experience through commercialization of our ACURATE TA™ maintaining the highest level of clinical result will drive our commercial strategy. We are very appreciative of our outstanding physicians and their expertise which supported the clinical development of the ACURATE TA™."

About the ACURATE TAVI™ product family:
The Symetis transapical TAVI system consists of the ACURATE TA™ Aortic Bioprosthesis and its Transapical Delivery System. The self-positioning bioprosthesis is composed of a non-coronary leaflet surgical quality porcine tissue valve sewn into a self-expanding nitinol stent that is covered with a PET-skirt. The Transapical Delivery System is designed for quick, 2-step deployment and simple positioning within the native annulus. The product is available in three sizes (S, M, L) to treat patients with aortic annulus diameters from 21mm to 27mm.

Based upon the same self-positioning concept, the Symetis transfemoral TAVI system (ACURATE TF™ Aortic Bioprosthesis) will begin its First-In-Man trial in Q4/2011.

The ACURATE TA™ Aortic Bioprosthesis and its Transapical Delivery System and the ACURATE TF™ Aortic Bioprosthesis are trademarks of SYMETIS S.A. Symetis products are protected by pending and granted patents, as well as by design and utility model rights. Additional information is available at www.symetis.com.

About Symetis
Symetis SA is a private Swiss company developing innovative, minimally invasive heart valve replacement solutions. 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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