



Symetis receives CE Mark approval for transfemoral transcatheter aortic heart valve system ACURATE *neo*[™], and launches product with first commercial implantations

Symetis joins industry leaders Edwards Lifesciences and Medtronic as only companies to offer both transapical and transfemoral options for transcatheter aortic heart valve delivery

Lausanne, Switzerland, September 12, 2014 – Symetis SA, the leading European developer of transcatheter aortic valve implantation (TAVI) systems, announced today the launch of ACURATE *neo*[™], its 15F compatible transfemoral TAVI system. Commercial implantations started early September after Symetis received CE Mark approval for ACURATE *neo* this summer.

Symetis conducted a single-arm, prospective, multicenter trial at six centers of excellence in Brazil, Germany and Japan enrolling 89 high-risk patients with severe, symptomatic aortic stenosis who were considered high-risk or non-surgical candidates for open-heart surgery. The primary endpoint was mortality at 30 days (3.4%). Secondary endpoints included procedure success (95%) and safety and performance data collected at 30 days, and at 6 and 12 months.

“With the transfemoral ACURATE *neo* the Symetis team successfully duplicated the intuitive use and solid performance that are the hallmarks of its transapical system ACURATE TA[™],” said principal investigator Prof. Helge Möllmann from the Department of Cardiology at the Kerckhof Klinik, Bad Nauheim, Germany.

“I found the ACURATE *neo* to be one of the easiest and most predictable transfemoral self-expanding TAVI systems, and its clinical performance outstanding,” said Prof. Alexandre Abizaid, from the Institute Dante Pazzanese de Cardiologia in São Paulo, Brazil, who conducted the Brazilian arm of the study.

“We are delighted with the performance and safety outcomes of our CE Mark study, along with its procedural success,” said Laura Brenton, VP Clinical & Regulatory of Symetis. “Reflecting an evolving European regulatory environment for medical devices, we brought over 90% of the patient cohort to the 12-month follow-up window. This is the most robust set of clinical data submitted for a TAVI CE Mark to date.”

The rollout of ACURATE *neo* will be modeled on the successful commercialization of Symetis’s transapical system, ACURATE TA, which has witnessed a remarkably rapid uptake in core European markets. “We look forward to working with heart teams across Europe that have gained experience with our transapical ACURATE TA to progressively establish ACURATE *neo* as a leading transfemoral TAVI solution,” said Jacques R. Essinger, CEO of Symetis. “With the launch of ACURATE *neo*, Edwards Lifesciences (NYSE:EW), Medtronic (NYSE: MDT), and Symetis are now the only companies offering dual access routes, transapical and transfemoral, for the delivery of transcatheter aortic heart valves.

Presentation at TCT Conference, Washington DC

Prof. Helge Möllmann will present a Technology Review, Clinical Results, and Case Examples of ACURATE *neo* on September 15, at 2:50pm, as part of the “Didactic Symposia: AORTIC VALVE THERAPIES – Today and Tomorrow” of the 26th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation.



About the ACURATE TAVI™ product family

The Symetis transfemoral TAVI system consists of the ACURATE *neo*™ Aortic Bioprosthesis and the ACURATE TF™ Transfemoral Delivery System. The self-positioning bioprosthesis is composed of a porcine pericardial tissue valve sewn into a self-expanding nitinol stent covered with an anti-leak porcine pericardial skirt. Its transfemoral delivery system is designed for a simple 3-step deployment and stable positioning within the native annulus. The product is compatible with the 15F Terumo Solopath or 18F Cook sheaths. The product is available in three sizes (S, M, L) to treat patients with aortic annulus diameters from 21mm to 27mm.

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 covered with an anti-leak PET skirt. Its transapical delivery system is designed for quick, sheathless 2-step deployment and tactile 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.

About Symetis

Symetis SA is a leading European developer of innovative, minimally invasive heart valve replacement devices. The company's products, ACURATE TA™ and ACURATE *neo*™ and their delivery systems, are based on proprietary geometry and delivery technologies and are well positioned to target the estimated \$2 billion TAVI market. For more information visit www.symetis.com.

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