Boston Scientific Announces First Commercial Implants Of The Lotus™ Valve System in Europe

Patients In Germany Receive New Transcatheter Aortic Valve Implantation Devices Specially Designed For Total Control And Accurate Deployment

Marking a major step forward in the evolution of Transcatheter Aortic Valve Implantation (TAVI) technology, the first two commercial implants of the Boston Scientific (NYSE: BSX) Lotus™ Valve System have taken place in a German hospital. Prof. Dr. med. Gerhard Schuler and Prof. Dr. med. Axel Linke, both considered TAVI pioneers, led the procedures at the Heart Center - University Hospital Leipzig, Germany. CE Mark approval for the Lotus Valve System was announced October 28, 2013 at the Transcatheter Cardiovascular Therapeutics (TCT) Conference in San Francisco.

The Lotus Valve System offers a unique and effective alternative treatment for patients with severe aortic stenosis at high risk of surgical valve replacement. It is a next-generation transcatheter aortic valve implantation (TAVI) device designed to give physicians total control throughout the TAVI procedure. The Lotus Valve is comprised of bovine pericardium and a nitinol frame with a central marker to aid in precise positioning. It features a novel Adaptive Seal™ technology to help minimize aortic regurgitation (leaking), a proven predictor of mortality. It is also the first device of its kind that can be fully retrieved, redeployed, or repositioned, including after full valve deployment and prior to release.

"The Lotus Valve System permits very precise positioning of the device and the Adaptive Seal minimizes potential paravalvular leakage," said Professor Schuler. "These are the key differentiating features of this new technology."

Primary endpoint data from the REPRISE II clinical trial were presented at TCT by Prof. Ian Meredith, principal investigator and director of MonashHeart at Monash Medical Centre, Melbourne, Australia. The data demonstrated that the Lotus Valve System was successfully implanted and correctly positioned in all 120 patients, and met the co-primary endpoints of mean aortic valve pressure gradient and all-cause mortality at 30 days. The valve produced impressive clinical results, with no valve malpositioning, migration, or severe embolization, low clinical event rates that were consistent with those reported for other valves, and negligible paravalvular aortic regurgitation at 30 days.

The Lotus Valve System comes pre-attached on a transfemoral delivery system and is inserted into the body through a small incision in the leg. Once delivered across the diseased aortic valve, the Lotus Valve System is deployed through a controlled mechanical expansion that is distinct from balloon-expandable or self-expanding valves.

"The controlled mechanical expansion and early functioning of the valve facilitate precise positioning on the first attempt, and the ability to fully or partially recapture the valve, if necessary, provides additional assurance that the valve will be ideally positioned at the end of the procedure," said Dr. Linke.

The Lotus Valve System is available at select centers in Europe with commercial site expansion accelerating as physicians and centers become fully trained. The valve is available in a 23mm and 27mm size, treating patients with aortic annulus sizes from 20mm to 27mm. The Lotus Valve System is an investigational device in the United States and Japan and is not available for sale in these countries.

"Completing our first commercial implants marks a key step forward in offering an advanced new technology in Europe. The Lotus Valve System has been designed to give the physician increased control during implantation and to help provide a more precise, predictable procedure," said Tom Fleming, vice president and general manager, Structural Heart, Boston Scientific. "We believe the Lotus Valve is an important treatment alternative for severe aortic valve disease patients at high risk for surgical valve replacement."

About Aortic Valve Disease
Aortic valve disease results in dysfunction of the aortic valve, one of the four valves that control the flow of blood in and out of the heart. Aortic valve stenosis is the process of thickening and stiffening in the valve, which can result in an abnormal narrowing of the aortic valve opening and reduction in blood flow. Aortic stenosis is a common problem affecting approximately three percent of the population over age 65 and five percent of people older than 75. From the onset of aortic stenosis symptoms, the average survival rate is 50 percent at two years and 20 percent at five years.

About Boston Scientific
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