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

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.

Cautionary Statement Regarding Forward-Looking Statements
This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding markets for our products, our business plans, clinical trials, product performance and competitive offerings. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the

future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A – Risk Factors in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A – Risk Factors in Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

1Kodali SK, et. al. Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement. NEJM 2012;366:1685, Link (Accessed: April 25, 2013)
2Tamburino C, et. al. Valvular Heart Disease. Circ 2011;123:299, Link (Accessed: April 25, 2013)
3Abdel-Wahab M et. al. Aortic regurgitation after transcatheter aortic valve implantation: incidence and early outcome. Results from the German transcatheter aortic valve implantation registry. Heart 2011;97:899, Link (Accessed: April 25, 2013)

ATTENZIONE: In alcuni paesi europei (Belgio, Bulgaria, Cipro, Estonia, Francia, Grecia, Irlanda, Italia, Lituania, Lussemburgo, Malta, Polonia, Paesi Bassi, Portogallo, Romania, Slovacchia, Slovenia, Spagna e Ungheria), la pubblicità di dispositivi medici presso il pubblico non è consentita. Pertanto, se stai visitando questo sito da uno dei paesi elencati e non sei un operatore sanitario, devi abbandonarlo immediatamente, poiché le informazioni visualizzate potrebbero non essere consentite dalla legge del tuo paese di residenza. Se ignori questo avviso, Boston Scientific declinerà ogni responsabilità che deriva dall'accesso alle informazioni contenute.

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