Boston Scientific

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

NATICK, Mass., Nov. 15, 2013 /PRNewswire/ -- 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 inSan 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 inEurope 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." To view and download an image of the Lotus Valve System, click here.

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
Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 30 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com and connect on Twitter and Facebook.

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, new product launches and launch cadence, regulatory approvals, clinical trials, product performance and importance, 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.

CONTACT:
Ryan Davenport
763-494-2664 (office)
Global Media Relations
Boston Scientific Corporation
media@bsci.com

Simonetta Balbi
+ 39 3387936422 (mobile)
+ 39 0106060281 (direct)
PR and Corporate Communication EMEA
Boston Scientific Corporation
Balbis@bsci.com

Michael Campbell
508-650-8023 (office)
Investor Relations
Boston Scientific Corporation
investor_relations@bsci.com

SOURCE Boston Scientific Corporation

---

https://news.bostonscientific.com/2013-11-15-Boston-Scientific-Announces-First-Commercial-Implants-Of-The-Lotus-Valve-System-in-Europe