Boston Scientific

Boston Scientific Receives CE Mark For The New 25 mm Lotus™ Valve System

European Launch Means Physicians Can Now Choose From Three Available Valve Sizes To Match Patient Anatomy More Precisely

MARLBOROUGH, Mass., July 14, 2014 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has received CE Mark and begun the European commercial launch of its new 25 mm Lotus™ Transcatheter Aortic Valve Implantation (TAVI) System, complementing the currently available 23 mm and 27 mm valve sizes.

"Having the 25 mm size allows us to be more precise in selecting the appropriate valve, which we anticipate will further improve outcomes for our patients," said Dr. Nicolas Van Mieghem at Erasmus Medical Center, Rotterdam, The Netherlands.

Prior to full commercialization, a limited market evaluation of the 25 mm valve Lotus Valve System was performed in select hospitals across Europe and Australia. Feedback on the valve performance was favorable from all implanting physicians.

"We have seen great results in the patients we have treated with the 25 mm Lotus Valve System," said DrSabine Bleiziffer from the German Heart Centre in Munich, Germany. "What I really like about the Lotus valve is that it provides a high level of precision during implantation, allowing me to feel in control. We look forward to treating more patients with this valve."

"The Lotus valve design helps simplify the procedure with the ability to assess valve functionality before release," said Prof. Dr. Peter Wenaweser from the Inselspital in Bern, Switzerland. "Adding a 25 mm valve makes sizing and valve selection even more precise."

Six-month outcomes of the REPRISE II clinical study were presented in May at EuroPCR in Paris. REPRISE II is evaluating the Lotus Valve System in symptomatic patients with severe aortic valve stenosis considered at high risk for surgical valve replacement. The study demonstrated that the Lotus Valve System delivered sustained safety and effectiveness outcomes out to six months, with only 1.1 percent of patients having moderate paravalvular aortic regurgitation as assessed by an independent core laboratory. No severe cases occurred.

"We believe the addition of the 25 mm valve size will offer our Lotus users an important treatment option for patients with severe aortic valve disease," said Tom Fleming, vice president and general manager, Structural Heart, Boston Scientific. "Commercializing the 25 mm valve only seven months after our initial launch of the Lotus Valve System demonstrates our commitment to advancing therapies and improving patient outcomes."

About the Lotus Valve System

The Lotus Valve System offers a unique and effective alternative treatment for patients with severe aortic stenosis at high risk of conventional surgical valve replacement. It is a differentiated second-generation TAVI technology, consisting of a pre-loaded, stent-mounted tissue valve prosthesis and catheter delivery system for guidance and percutaneous placement of the valve. The low-profile delivery system and introducer sheath are designed to enable predictable and precise placement associated with early valve function, as well as bi-directional atraumatic repositioning and retrieval at any time prior to release of the aortic valve implant. Rapid pacing is not required. The device also features a unique Adaptive Seal designed to minimize the incidence of paravalvular regurgitation, which has proven to be a predictor of mortality.[1, 2, 3] The Lotus Valve System has CE Mark approval and is available for sale in CE Mark countries. In the U.S., the Lotus Valve System is not available for sale.

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 the age of 65 and five percent of people older than 75. From the onset of symptomatic aortic stenosis, the average survival rate is 50 percent at two years and 20 percent at five years.

1. Kodali SK, et. al. Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement. NEJM 2012;366:1685 (Accessed: April 25, 2013)

2. Tamburino C, et. al. Valvular Heart Disease. Circ 2011;123:299 (Accessed: April 25, 2013)

3. Abdel-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 (Accessed: April 25, 2013)

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, our business plans, clinical trials, our technology, product performance and impact, 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.

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