Boston Scientific Receives CE Mark For LOTUS Edge™ Valve System

Boston Scientific Corporation (NYSE: BSX) has received CE Mark for the LOTUS Edge™ Valve System, the company's next generation transcatheter aortic valve implantation (TAVI) technology. The LOTUS Edge valve system is indicated for aortic valve replacement in patients with severe aortic stenosis who are considered at high risk for surgical valve replacement. Instead of open heart surgery, the replacement valve is delivered via transcatheter percutaneous delivery, a minimally invasive procedure involving a small incision to gain access to a blood vessel.

In comparison to the Lotus™ Valve System, this next iteration incorporates a more flexible, lower profile catheter designed to improve ease of use and accommodate tortuous anatomy. Another differentiating feature of the LOTUS Edge valve system is the inclusion of Depth Guard™, a design element intended to reduce the need for a permanent pacemaker (PPM).

“The LOTUS Edge device is a highly anticipated next generation of the Lotus Valve System,” said Professor Ian Meredith, director of MonashHeart, at Monash Medical Centre in Melbourne, Australia. “It retains many of its predecessor’s unique and valuable proprietary features, including the ability to reposition the device precisely and prevent paravalvular leak, while incorporating new design characteristics such as a more flexible catheter for easier delivery and Depth Guard™ technology designed to reduce valve interaction with the conduction system of the heart during valve deployment.”

Leveraging the current Lotus platform, the LOTUS Edge valve system integrates the Adaptive Seal™ technology which minimizes paravalvular regurgitation (leaking) or PVL, as demonstrated in the 1,000 patient RESPOND Post-Market Registry. This study found that 91.9% of patients had core-lab adjudicated trace or no PVL pre-discharge, and 7.7% had mild PVL. No patients had severe PVL and only 0.3% of patients had moderate PVL. LOTUS Edge continues to be the only TAVI device that offers controlled mechanical expansion, which allows the valve to be fully deployed and assessed and then repositioned or fully retrieved by the physician, if needed.

“We are steadfast in our commitment to advancing the science behind TAVI procedures by ensuring clinicians have effective treatment modalities to provide to their patients with severe aortic stenosis,” said Kevin Ballinger, president, Interventional Cardiology, Boston Scientific. “The LOTUS Edge valve system is designed to give physicians increased control during implantation, which can help provide a more precise, predictable procedure to ensure the best patient outcomes.”

The LOTUS Edge valve system will be available to select centers in Europe, with commercial site expansion accelerating as physicians and centers become fully trained.

The Lotus Valve System is an investigational device in the United States and Japan and is not available for sale in those countries.

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 of the valve, resulting in restricted 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 35 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.eu 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 our business plans, regulatory approvals and product performance and impact. 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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