Boston Scientific Receives CE Mark For Lotus™ Valve System

Transcatheter Aortic Valve Replacement (TAVR) Device Offers Precise Positioning and Placement, Offering Physicians Unprecedented Control

Boston Scientific Corporation (NYSE: BSX) has received CE Mark for the Lotus™ Valve System, the company's advanced transcatheter aortic valve replacement (TAVR) technology. This key approval offers a unique and effective new treatment alternative for patients with severe aortic stenosis at high risk

The Lotus Valve System is immediately available to select centers in Europe, with commercial site expansion accelerating as physicians and centers become fully trained.

The Lotus Valve System is designed to provide physicians increased control during implantation and to help provide a more precise, predictable procedure. It is the only aortic valve device that can be assessed in its final position prior to release, while maintaining the ability for the physician to reposition or fully resheath and retrieve the valve. The Lotus Valve System also incorporates a unique Adaptive Seal™ technology designed to minimize aortic regurgitation (leaking), a proven predictor of mortality.

"The ability to initially position the Lotus Valve precisely and, if needed, to easily reposition or fully retrieve the valve provides the operator with remarkable control," said Professor Ian Meredith, director of MonashHeart at Monash Medical Centre in Melbourne, Australia, and principal investigator of the REPRISE II trial. "Combined with early and often complete elimination of aortic regurgitation as observed in REPRISE II, the unique features of the Lotus Valve technology represent a significant step forward in the percutaneous treatment of eligible patients with severe symptomatic aortic stenosis."

Data presented at the PCR London Valves course in September demonstrated the Lotus Valve System met the primary performance endpoint for the first 60-patient cohort and was implanted successfully in all patients (60/60) with no cases of severe paravalvular regurgitation. In 76.1 percent of patients there was no corelab adjudicated paravalvular regurgitation at six months.

"Results from the REPRISE II trial highlight the promise behind the Lotus Valve System, especially related to avoiding moderate or severe paravalvular leaks," said Dr. Nicolas M. Van Mieghem, M.D., Erasmus Medical Center in Rotterdam, The Netherlands. "In addition to providing a new treatment option for TAVR, the Lotus Valve has the potential to improve clinical outcomes by minimizing paravalvular leaks."

"The Lotus Valve System offers patients a new, effective treatment option and provides physicians unmatched positioning and placement capabilities," said Tom Fleming, vice president and general manager, Structural Heart, Boston Scientific. "It's the culmination of a decade of research and development and demonstrates our commitment to innovations that make a difference in the lives of patients."

The Lotus Valve System comes pre-loaded on a transfemoral delivery system which is inserted through a small incision in the leg. Available in a 23mm and 27mm size, the Lotus Valve System can treat patients with aortic annulus sizes from 20 mm to 27 mm. 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 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, new product launches and launch cadence, regulatory approvals, clinical trials, 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.

---

https://news.bostonscientific.eu/2013-10-28-Boston-Scientific-Receives-CE-Mark-For-Lotus-TM-Valve-System