Boston Scientific

First Patient Enrolled in REPRISE II TAVR Clinical Trial to Evaluate the Safety and Performance of the Lotus™ Valve System

REPRISE II Study Results Expected to Support CE Mark and Other Regulatory Filings

NATICK, Mass., Oct. 10, 2012 /PRNewswire/ -- Boston Scientific (NYSE: BSX) has enrolled the first patient in the REPRISE II clinical trial to evaluate the safety and performance of the Lotus™ Valve System in up to 120 patients with severe aortic valve disease. This international, multi-center study includes 15 sites in Australia, France, Germany and the United Kingdom. The Lotus Valve System is the first transcatheter aortic valve replacement (TAVR) device of its kind that is designed to minimize aortic regurgitation (leaking). The device is both fully repositionable and retrievable prior to release, offering predictable and precise placement. The results of the REPRISE II trial are expected to be used to support CE mark and other international regulatory approvals.

"We were encouraged by the promising results of the REPRISE I clinical trial completed earlier this year and we are therefore very confident about evaluating the safety and performance of the Lotus Valve in a larger patient cohort," said Ian Meredith, Professor and Director of Monash Heart, at Monash Medical Centre in Melbourne, Australia and the principal investigator of the REPRISE II trial. "The Lotus Valve has a number of important features which address some of the limitations observed with the first generation devices. The ease of use, predictable and precise positioning, and the ability to fully reposition and retrieve the Lotus Valve offer the operator considerable reassurance and control. These features, along with the minimized risk of paravalvular leakage, may lead to improved clinical outcomes."

The Lotus Valve System is a differentiated second-generation TAVR technology, which consists of a pre-loaded, stent-mounted tissue valve prosthesis and catheter delivery system used for guidance and percutaneous placement of the valve. The low-profile delivery system and introducer sheath are designed to enable predictable and precise placement, as well as bi-directional atraumatic repositioning and retrieval at any time prior to release of the aortic valve implant. The device also employs a unique Adaptive Seal™ feature designed to minimize the incidence of paravalvular regurgitation, which has proven to be a predictor of mortality.

Current study enrollment requires that patients have severe calcific aortic stenosis, are aged 70 years or older and are considered to be at high surgical risk, defined as an STS (Society of Thoracic Surgeons), Mortality score >8 or the consensus opinion of the Heart Team. The REPRISE II study is designed to study two valve sizes, 23 mm and 27 mm, and have a 5-year follow-up. Beyond that, it will assess for other endpoints recommended by the Valve Academic Research Consortium (VARC) and regulatory agencies. Study enrollment is expected to be completed in the first half of 2013.

"There is a high need for continued evolution of device technology to treat people with severe aortic valve disease," said Keith D. Dawkins, M.D., global chief medical officer for Boston Scientific. "We are looking forward to advancing the Boston Scientific valve program with REPRISE II, as we believe the Lotus Valve System is a unique technology that will offer interventional cardiologists greater precision and control in deployment which, in effect, may simplify the implantation procedure and lead to improved patient outcomes."

The Lotus Valve System is an investigational device, limited by applicable law to investigational use and not available for sale. The device was developed by Sadra Medical, which Boston Scientific acquired in 2011. For more information, visit www.sadramedical.com.

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 3 percent of the population over age 65 and 5 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.

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Patient Testimonial

To view a patient testimonial about the Lotus Valve System, please CLICK HERE.

About Boston Scientific

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices that are used in a broad range of interventional medical specialties. For more information, please visit: www.bostonscientific.com.

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, markets for our products, regulatory approvals, clinical trials and effects, and product performance and importance. 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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