Boston Scientific

Boston Scientific Lotus™ Valve System Meets Primary Performance Endpoint In REPRISE II Trial

New Data Announced At TCT 2013 Demonstrate Successful Deployment In All 120 Patients With No Severe Paravalvular Regurgitation At 30 Days

San Francisco, Oct. 31, 2013 /PRNewswire/ -- The Boston Scientific Corporation (NYSE: BSX) Lotus™ Valve System met a key performance measure in the treatment of symptomatic patients with severe aortic valve stenosis considered at high risk for surgical valve replacement, according to new data released today at the Transcatheter Cardiovascular Therapeutics (TCT) Conference in San Francisco.

Data presented as a First Report Investigation by Professor Ian Meredith, director of MonashHeart at Monash Medical Centre in Melbourne, Australia, and principal investigator of the REPRISE II Trial, demonstrated that the Lotus Valve System, which was implanted successfully in all 120 patients, met the primary device performance endpoint at 30 days with no severe paravalvular aortic regurgitation (leaking).

The Lotus Valve System is a differentiated second generation transcatheter aortic valve replacement (TAVR) device designed for total control. It is both fully repositionable and retrievable prior to release, with a unique Adaptive Seal™ technology designed to minimize paravalvular aortic regurgitation, a proven predictor of mortality.[1,2,3]

"The results from the REPRISE II trial continue to demonstrate the benefits of the Lotus Valve System, particularly the ability to position the valve accurately the first time, while having the advantage of full retrieval if needed," said Meredith. "In all 120 patients, the Lotus Valve System was successfully implanted and positioned appropriately with negligible aortic regurgitation while reporting low 30-day all-cause mortality and major stroke rates in this sick patient population. This is a testament to the advancement in technology that the Lotus Valve System offers."

REPRISE II is an ongoing prospective, single-arm study that has enrolled 120 patients at 14 sites in Australia, France, Germany and the UK. REPRISE II is being extended to enroll an additional 130 patients at twenty sites in Australia and Europe.

Key findings included:

- The primary device performance endpoint assessed by an independent core lab was met as the 30-day mean aortic valve pressure gradient of 11.5±5.2 mmHg was significantly ($P<0.001$) less than the performance goal of 18 mmHg.
- The primary safety endpoint, defined as all-cause mortality at 30 days, was 4.2 percent.
- Independent core lab assessment of paravalvular aortic regurgitation at 30 days indicated no severe regurgitation and one case of moderate regurgitation (1.0 percent). In 5.2 percent of patients regurgitation was considered trace and in 78.4 percent of patients there was no paravalvular regurgitation at 30 days.
- No instances of non-study valve implantation, unplanned use of cardiopulmonary bypass, valve embolization, valve-in-valve or ectopic valve placement occurred.
- The disabling stroke rate for the 120 patients at 30 days was 1.7 percent.

One-year results from REPRISE I, a prospective, single-arm feasibility study on patients with severe symptomatic aortic stenosis conducted in Australia, were presented in May at EuroPCR by Professor Meredith and published online ahead of print by EuroIntervention. The data demonstrated sustained safety and performance of the Lotus Valve out to one year with no new major adjudicated events, as defined by the Valve Academic Research Consortium (VARC), and no moderate or severe paravalvular aortic regurgitation in any patient.

"These new results from the REPRISE clinical trial program, and particularly those from the REPRISE II trial, underscore the unique technology behind the Lotus Valve System," said Keith Dawkins, M.D., global chief medical officer, Boston Scientific. "These features lead to a predictable implantation procedure and may result in improved clinical outcomes. The Lotus Valve offers a novel TAVR option for patients with severe aortic valve disease considered at high risk for surgical valve replacement."

About the Lotus Aortic Valve System
The Lotus Aortic Valve System is a differentiated second-generation TAVR 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. 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. The Lotus Valve System has CE Mark approval and is available for sale in Europe and CE Mark countries. In the U.S., the Lotus Valve System is an investigational device and 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 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.

1. Kodali SK, et. al. Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement. NEJM 2012;366:1685, http://www.nejm.org/doi/full/10.1056/NEJMoa1200384 (Accessed: April 25, 2013)

2. Tamburino C, et. al. Valvular Heart Disease. Circ 2011;123:299, http://circ.ahajournals.org/content/123/3/299.full (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, http://circ.ahajournals.org/content/123/3/299.full (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, clinical trials and importance of their results, 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.

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