Boston Scientific

REPRISE II Data Demonstrate Sustained Safety And Performance Outcomes At One Year For The Boston Scientific Lotus™ Valve System

No Cases of Moderate or Severe Paravalvular Aortic Regurgitation at One Year

MARLBOROUGH, Mass., Sept. 15, 2014 /PRNewswire/ -- New data from the Boston Scientific (NYSE: BSX) clinical trial program of the Lotus™ Valve System continue to demonstrate strong performance as a less invasive treatment for patients with severe aortic stenosis who are considered high risk for surgical valve replacement.

Data from the REPRISE II clinical trial confirmed safety and effectiveness out to one year, with more than 86 percent of patients exhibiting a complete absence of paravalvular aortic regurgitation (leaking) and no patients demonstrating moderate or severe paravalvular aortic regurgitation. New data from the REPRISE I and REPRISE II clinical trials were presented at the 26th Transcatheter Cardiovascular Therapeutics (TCT) meeting, the annual scientific symposium of the Cardiovascular Research Foundation.

REPRISE II is an ongoing prospective, single-arm, multi-center study designed to evaluate safety and performance of the Lotus Valve System for symptomatic patients with severe calcific aortic stenosis who are considered high risk for surgical valve replacement. The study enrolled 120 patients at 14 sites in Australia, France, Germany and the UK.

In REPRISE II, key one-year results include the following:

- Mean aortic valve pressure gradient remained low and stable at 12.6$\pm$ 5.7 mmHg.
- More than 86 percent of patients had no paravalvular aortic regurgitation by independent core lab assessment. In addition, no cases of moderate or severe paravalvular aortic regurgitation occurred. Mild and trace paravalvular aortic regurgitation rates were low at 11.4 and 2.3 percent, respectively.
- Cardiovascular mortality rate was 6.7 percent.
- Disabling stroke rate was 3.4 percent.
- No cases of non-study valve implantation, unplanned use of cardiopulmonary bypass, valve embolization, valve-in-valve or ectopic valve placement occurred.

"The one-year REPRISE II data show strong and sustained clinical benefits, excellent valve hemodynamics and remarkably low rates of paravalvular regurgitation and cardiovascular mortality," said Professor Ian Meredith, director of MonashHeart at Monash Medical Centre in Melbourne, Australia, and principal investigator of the REPRISE II trial. "These positive data reinforce the benefits and features of the Lotus Valve System including the ability to achieve precise primary valve placement, reposition or fully retrieve if needed, and minimize if not obliterate paravalvular regurgitation with an effective Adaptive Seal™."

REPRISE II data build on the positive findings from REPRISE I, a prospective, single-arm, feasibility study that evaluated 11 patients. The REPRISE I two-year results also demonstrated no instances of moderate or severe paravalvular leak and no instances of death. Additionally, patients who received the Lotus Valve System had durable and significant improvements in valve area, transvalvular pressure gradients and New York Heart Association classification compared to baseline.

"We are pleased that these REPRISE I and II data demonstrate excellent and sustained results with no moderate or severe paravalvular aortic regurgitation," said Keith Dawkins, M.D., global chief medical officer, Boston Scientific. "The Lotus Valve System, with its unique technology, has the potential to address an unmet need and improve clinical outcomes for patients with severe aortic stenosis."

About the Lotus Valve System

The Lotus Aortic Valve System 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. The device also features a unique Adaptive Seal™ designed to minimize the incidence of paravalvular regurgitation, which has been identified as a predictor of mortality in multiple clinical trials.[i,ii,iii]

In the U.S., the Lotus Valve System is not available for sale. It is a CE marked device, available for sale in countries where CE marking is the regulation in force.

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.

About Boston Scientific
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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, presentations, clinical trials and impact of data, 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.

CONTACTS:
Media: Ryan Davenport
Global Media Relations
Boston Scientific Corporation
612-240-0492 (cell)
media@bsci.com

Investors: Susie Lisa, CFA
508-683-5565 (office)
Investor Relations
Boston Scientific Corporation
investor_relations@bsci.com

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

[iii] 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)

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