Boston Scientific

Boston Scientific Announces Positive Data From Lotus™ Transcatheter Aortic Valve Trial

NATICK, Mass., May 15, 2012 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announces results from the REPRISE I feasibility trial, which evaluated the acute safety of the Lotus™ Aortic Valve System in patients with severe aortic valve disease. The Lotus Aortic Valve System is the first transcatheter aortic valve replacement (TAVR) device of its kind that is designed to minimize aortic regurgitation (leaking) and is both fully repositionable and retrievable prior to release. Data presented today at the annual EuroPCR Scientific Program in Paris demonstrated successful deployment of the valve in all patients with virtually no paravalvular regurgitation after valve placement or at discharge.

"Perhaps the most impressive feature of the Lotus Valve System in this study was the ability to precisely position the valve on the first attempt, eliminating the need for repositioning, although this capability was available if needed," said Ian Meredith, Professor and Director of MonashHeart, at Monash Medical Centre in Melbourne, Australia, and principal investigator of the REPRISE I Trial. "Another striking feature was that the valve operated early in the deployment process, providing us some comfort and time to consider the valve position, as well as the immediate and almost complete obliteration of aortic regurgitation even in patients who had moderately severe aortic regurgitation after balloon valvuloplasty. In this regard, I think the Lotus valve technology is somewhat unique."

REPRISE I is a prospective, single-arm feasibility study that enrolled 11 patients at three sites in Australia.The primary endpoint is defined as successful device implantation without in-hospital major adverse cardiovascular or cerebrovascular events (MACCE) through discharge or seven days post-procedure (whichever comes first). In-hospital MACCE includes death, heart attack, major stroke, and conversion to surgery or repeat procedure due to valve-related dysfunction. All patients had severe symptomatic aortic stenosis and were considered at high risk for surgical valve replacement. No in-hospital MACCE were reported in 91 percent (10 of the 11) of patients. One stroke and no deaths were observed. No moderate or severe paravalvular regurgitation was present after valve placement or at discharge.

The Lotus Aortic Valve System is a differentiated second-generation TAVR technology, which consists 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, 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 REPRISE I results underscore the unique technology behind the Lotus Aortic Valve System, which offers interventional cardiologists greater precision and control in deployment while at the same time minimizing the occurrence of aortic regurgitation. These features help to simplify the implantation procedure, and will potentially lead to improved clinical outcomes," said Keith D. Dawkins, M.D., global chief medical officer for Boston Scientific. "We look forward to advancing the Lotus Aortic Valve System clinical program by initiating patient enrollment in the REPRISE II study later this year."

The REPRISE II trial is designed to evaluate the safety and performance of the Lotus Aortic Valve System in 120 patients at up to 15 sites in Australia and Europe. Data from the trial are expected to be used to support CE Mark and other international regulatory approvals. Enrollment is expected to be completed in the first half of 2013.

The Lotus Aortic 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.

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, regulatory approvals, clinical trials and clinical outcomes, product performance 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.

CONTACT:

Steven Campanini
508-652-5740 (office)
Media Relations
Boston Scientific Corporation
steven.campanini@bsci.com

Geraldine Varoqui
+491707828558 (mobile)
Media Relations EMEA
Boston Scientific Corporation
geraldine.varoqui@bsci.com

Lorie Fiber
310-623-0404 (mobile)
Media Relations
Weber Shandwick
lfiber@webershandwick.com

Sean Wirtjes
508-652-5305 (office)
Investor Relations
Boston Scientific Corporation
investor_relations@bsci.com

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