Boston Scientific

Boston Scientific Completes Enrollment in Clinical Trial to Evaluate Lotus™ Aortic Valve System

NATICK, Mass., April 23, 2012 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announces that it has completed enrollment in the REPRISE I clinical trial, which is designed to evaluate the acute safety of the Lotus™ Aortic Valve System, the first transcatheter aortic valve replacement (TAVR) device of its kind for patients with severe aortic valve stenosis that is both fully repositionable and retrievable prior to release. This prospective, single-arm feasibility study enrolled 11 patients at three sites in Australia. Results from the REPRISE I trial are scheduled to be presented at the EuroPCR Congress in May.

"We are delighted to complete enrollment in this important trial, and pleased that the clinical results will be presented at the forthcoming EuroPCR conference in Paris next month," said Ian Meredith, Professor and Director of MonashHeart, at Monash Medical Centre in Melbourne, Australia, and principal investigator of the REPRISE I Trial. "The Lotus Aortic Valve System offers the unique ability to precisely position the valve during deployment with the added ability to reposition and retrieve the device if necessary. The valve functions remarkably early in the deployment process, offering interventional cardiologists greater control over the deployment. We observed virtually no aortic regurgitation in all cases immediately after implantation."

The primary endpoint of the REPRISE I trial is defined as clinical procedural success 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. Secondary endpoints under study include successful repositioning of the Lotus Valve System (if attempted) and incidence of aortic valve regurgitation (leaking).

The Lotus Aortic Valve System 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.

"We are very encouraged by positive feedback from the REPRISE I investigators and look forward to the results of the study," said Keith D. Dawkins, M.D., global chief medical officer for Boston Scientific. "The Lotus Aortic Valve System is a truly differentiated second-generation TAVR technology designed to simplify and improve the entire aortic valve replacement procedure."

Boston Scientific expects to begin enrollment later this year in the REPRISE II study, which 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 will 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.

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 new product launches and launch cadence, regulatory approvals, clinical trials, product performance, clinical outcomes 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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