Boston Scientific

Boston Scientific Enrolls First Patients In U.S. Trial Of The Lotus™ Valve System

Data From REPRISE III Clinical Trial Designed to Support U.S. Regulatory Approval

MARLBOROUGH, Mass., Sept. 23, 2014 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has initiated the REPRISE III clinical trial, a pivotal study to evaluate the safety and effectiveness of the Lotus™ Valve System in patients with severe aortic stenosis and who are considered to be at either high or extreme risk for surgical valve replacement. The Lotus Valve System is the first transcatheter aortic valve replacement (TAVR) device that is both fully repositionable and retrievable prior to release.

Ted E. Feldman, M.D., director, Cardiac Catheterization Laboratory, NorthShore University HealthSystem in Evanston, Ill., and Michael Reardon, M.D., professor of cardiothoracic surgery at The Methodist DeBakey Heart & Vascular Center in Houston, are co-principal investigators of the REPRISE III study.

A clinical team led by Dr. Feldman implanted the first three Lotus Valve Systems this week at Evanston Hospital as part of the REPRISE III clinical trial. The initiation of the REPRISE III clinical trial marks the beginning of the process required to support U.S. Food and Drug Administration premarket approval.

Aortic valve stenosis is the process of thickening and stiffening in the valve, which results in a reduction in blood flow. It is a common problem affecting approximately three percent of the population age 65 and older, and five percent of people older than 75. From the onset of symptomatic aortic stenosis, the average survival rate is 50 percent at two years and 20 percent at five years. The REPRISE III trial aims to build on strong data from the REPRISE I and REPRISE II clinical studies, which have demonstrated sustained safety and performance outcomes for the Lotus Valve System.

"New data from REPRISE I and REPRISE II, which were presented last week at TCT 2014 in Washington, D.C., demonstrate remarkably low rates of paravalvular leakage and all-cause mortality," said Dr. Feldman. "We believe that REPRISE III, which is slated to involve more than 1,000 patients, will confirm these data and show that the Lotus Valve System has the potential to improve patient outcomes beyond what we've seen with first generation devices."

REPRISE III is a randomized, open-label study assessing the Lotus Valve System against an active comparator (CoreValve® TAVR System).

The primary endpoints of the study are:

- Safety: composite of all-cause mortality, stroke, life-threatening and major bleeding events, stage two or three acute kidney injury or major vascular complications at 30 days.
- Efficacy: composite of all-cause mortality, disabling stroke or moderate or greater paravalvular aortic regurgitation (leaking) at one year following procedure.

"Completing the first patient implantations of the Lotus Valve System as part of the REPRISE III IDE trial marks an important step in bringing this innovative technology to physicians and patients in the U.S.," said Tom Fleming, vice president and general manager, Structural Heart, Boston Scientific. "It demonstrates the commitment of Boston Scientific to building upon a body of clinical evidence and advancing care for patients who suffer from this debilitating disease."

For more information about REPRISE III, including patient eligibility, visit www.clinicaltrials.gov/ct2/show/NCT02202434?term=REPRISE+III+Lotus+Valve&rank=1.

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 is 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. Rapid pacing is not required during implantation. 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 an investigational device and not available for sale. It is CE marked in the European Union.

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 35 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, 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.

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[i] Kodali SK, et. al. Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement. NEJM 2012;366:1685 (Accessed: April 25, 2013)

[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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