Boston Scientific

Boston Scientific Initiates the RESPOND Post Market Registry Evaluating Clinical Outcomes in Patients Implanted With Lotus™ Valve System

NATICK, Mass., June 4, 2014 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has initiated the RESPOND Post Market Registry to assess real world performance of the Lotus™ Valve System. The RESPOND Registry will collect data on clinical outcomes and device performance in 1,000 patients implanted at 50 centers around the world.

Three patients enrolled in the RESPOND Registry thus far have been successfully implanted with the Lotus Valve System. Dr. Nicolas Van Mieghem and Prof. Peter De Jaegere led the first transcatheter aortic valve implantation (TAVI) procedure at Erasmus Medical Center in Rotterdam, the Netherlands using the Boston Scientific Safari™ Pre-Shaped TAVI Guidewire. The Safari Guidewire, which received FDA clearance and CE Mark in 2013, is compatible with the Lotus Valve System and other TAVI devices and is designed to facilitate stable, atraumatic valve placement.

The RESPOND Registry is a prospective, open label, single arm, multi-center, observational post market study. Clinical follow-up is at discharge, 30 days, 12 months and annually through five years. It features a primary endpoint of all-cause mortality compared to a performance goal, plus secondary endpoints using Valve Academic Research Consortium guidelines and definitions. An independent core laboratory will analyze the echocardiographic images and an independent clinical events committee will adjudicate key clinical events. These measures are designed to increase the quality of the collected data and address inconsistencies with site-reported data commonly observed in post market studies.

"It's a great privilege to kick off the RESPOND Registry with this first implant," said Dr. Van Mieghem, co-lead principal investigator of the RESPOND Registry. "The Lotus Valve System truly is an elegant and novel transcatheter valve concept providing a high level of precision and control. It simplifies the TAVI procedure by having the ability to assess valve functionality fully before release, which helps ensure optimal valve placement and a positive clinical outcome."

The Lotus Valve System offers a unique and effective treatment for patients with severe aortic stenosis at high risk of surgical valve replacement. It is a next-generation TAVI device designed to give physicians total control throughout the TAVI procedure.

"The Lotus Valve System functions early and allows for precise valve placement without the need for temporary pacing during deployment," said Keith Dawkins, M.D., global chief medical officer, Boston Scientific. "Differentiated features include an Adaptive Seal™ that minimizes paravalvular leakage, which was confirmed in the results of the REPRISE clinical program."

REPRISE II six-month outcomes were presented at EuroPCR 2014 in Paris. The clinical study demonstrated that the Lotus Valve System delivered sustained safety and effectiveness outcomes out to six months, with only 1.1 percent of patients having moderate paravalvular aortic regurgitation (leaking). No severe cases occurred. REPRISE II is evaluating the Lotus Valve System in symptomatic patients with severe aortic valve stenosis considered at high risk for surgical valve replacement.

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 proven to be a predictor of mortality.[1, 2, 3] The Lotus Valve System has CE Mark approval and is available for sale in CE Mark countries. In the U.S., the Lotus Valve System is not available for use or 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 our business plans, markets for our products, clinical trials, our technology, 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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