Post-market study evaluating the Lotus™ Valve System demonstrates extremely low PVL rates

Compelling Results Presented at EuroPCR 2015 Add to Growing Body of Evidence Supporting Performance and Safety

A new study evaluating the Boston Scientific (NYSE: BSX) Lotus™ Valve System demonstrated an extremely low rate of paravalvular aortic regurgitation (leakage) for a transcatheter aortic replacement valve, plus a cardiovascular mortality rate of less than two percent at 30 days.

Thirty day results for the first 250 patients in the RESPOND Post-Market Study were presented at EuroPCR 2015 in Paris by Nicolas M. Van Mieghem, M.D., co-principal investigator, Erasmus Medical Center in Rotterdam, the Netherlands. Key findings include the following:

- more than 95 percent of patients at hospital discharge had no or trace paravalvular aortic regurgitation (PVL), less than 5 percent had mild PVL and no patients exhibited moderate or severe PVL (as assessed by an independent core lab);
- the cardiovascular mortality rate was 1.6 percent at 30 days; and
- the mean pressure gradient and effective orifice area (EOA), measures used to assess the hemodynamic performance of the valve, were 10.1 ± 3.7 mmHg and 1.9 cm2 ± 0.4 (both $p<0.001$ vs. baseline).

“These first post-market study data from the RESPOND trial demonstrate that the Lotus Valve System can be used in clinical practice with an excellent safety profile and unprecedented low PVL rates,” said Dr. Van Mieghem. “The absence of PVL is associated with favorable long-term survival.”

In addition, rates and predictors for PVL were reported today from the REPRISE II Extended Cohort by Daniel Blackman, M.D., Leeds General Infirmary, Leeds, England. Key findings in the trial, involving 250 patients evaluated at 30 days post implantation, include the following:

- nearly 86 percent of patients had either no PVL or trace PVL; less than 14 percent had mild PVL and less than 1 percent had moderate PVL (as assessed by an independent core lab);
- no patients had severe PVL; and
- significant independent predictors of PVL included device: annulus area ratio and calcium volume.

Strong performance results from both studies continue to reinforce this therapy as a less invasive treatment alternative for patients with severe aortic valve stenosis who are considered to be at high risk for surgical valve replacement.

“These results are further evidence that the Lotus valve design, its precise placement and redeployment capabilities and its low rates of paravalvular regurgitation can make a significant and meaningful difference in the lives of patients,” said Keith D. Dawkins, M.D., global chief medical officer, Boston Scientific.

About the Lotus Valve System
The Lotus Valve System is a differentiated next-generation transcatheter aortic valve implantation (TAVI) device, consisting of a pre-attached, stent-mounted tissue valve prosthesis and catheter delivery system for guidance and percutaneous placement of the valve. It is the first device of its kind that offers controlled mechanical expansion, which allows the valve to be fully deployed, assessed and then released, providing unparalleled control during the procedure. The early valve function provides hemodynamic stability throughout the procedure and if necessary, the valve can be completely repositioned at any time prior to release. 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 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
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.eu 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.

i). Kodali SK, et. al. Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement. NEJM 2012;366:1685, https://www.nejm.org/doi/full/10.1056/NEJMoa1200384. Accessed: April 25, 2013.

ii). Tamburino C, et. al. Valvular Heart Disease. Circ 2011;123:299,https://circ.ahajournals.org/content/123/3/299.full. 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, https://circ.ahajournals.org/content/123/3/299.full. Accessed: April 25, 2013.

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