Boston Scientific Lotus™ Valve System Demonstrates Strong Performance And Safety Profile At Six Months [EN]

Only 1.1 Percent of Patients Experienced Moderate Paravalvular Aortic Regurgitation; No Severe Cases Occurred

Further validating its advanced transcatheter aortic valve implantation (TAVI) technology, the Boston Scientific Corporation (NYSE: BSX) Lotus™ Valve System continued to demonstrate impressive performance at six months, according to new data presented at EuroPCR 2014 in Paris.

Results from the REPRISE II clinical trial 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. The data were presented by Professor Ian Meredith, director of MonashHeart, at Monash Medical Centre in Melbourne, Australia, and principal investigator of the REPRISE II trial. The study is evaluating the Lotus Valve System in symptomatic patients with severe aortic valve stenosis considered at high risk for surgical valve replacement.

In REPRISE II, the key six-month findings include the following:

- The primary device performance endpoint of 30-day mean aortic valve pressure gradient, as assessed by an independent core lab, was met as the 30-day mean aortic valve pressure gradient of 11.5 +/- 5.2mmHg was significantly less than the performance goal of 18 mmHg (P<0.001). At six months, the mean aortic valve pressure gradient remained low and stable at 11.4 +/- 4.6 mmHg.

- An impressive 79.8 percent of patients had no paravalvular aortic regurgitation by independent core lab assessment. In addition, no cases of severe paravalvular aortic regurgitation occurred in any patient at six months.

- The all-cause mortality rate was 8.4 percent.

- The disabling stroke rate was 3.4 percent.

- No cases of non-study valve implantation, unplanned use of cardiopulmonary bypass, valve embolization, valve-in-valve or ectopic valve placement occurred.

"These new results from the REPRISE II clinical trial program underscore the unique technology behind the Lotus Valve System," said Keith Dawkins, M.D., global chief medical officer, Boston Scientific. "These features are designed to provide a predictable implantation procedure and may result in improved clinical outcomes. The Lotus Valve offers a novel TAVI option for patients with severe aortic valve disease considered at high risk for surgical valve replacement."

REPRISE II is an ongoing prospective, single-arm study that enrolled 120 patients at 14 sites in Australia, France, Germany and the UK. The trial was extended to an additional 130 patients at 16 sites in Australia and Europe. Enrollment in this extension of REPRISE II is now complete.

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. 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 an investigational device and not available for 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.

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, 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.

1Kodali SK, et. al. Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement. NEJM 2012;366:1685, Link (Accessed: April 25, 2013)
2Tamburino C, et. al. Valvular Heart Disease. Circ 2011;123:299, Link (Accessed: April 25, 2013)
3Abdel-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, Link (Accessed: April 25, 2013)

ATTENZIONE: In alcuni paesi europei (Belgio, Bulgaria, Cipro, Estonia, Francia, Grecia, Irlanda, Italia, Lituania, Lussemburgo, Malta, Polonia, Paesi Bassi, Portogallo, Romania, Slovacchia, Slovenia, Spagna e Ungheria), la pubblicità di dispositivi medici presso il pubblico non è consentita. Pertanto, se stai visitando questo sito da uno dei paesi elencati e non sei un operatore sanitario, devi abbandonarlo immediatamente, poiché le informazioni visualizzate potrebbero non essere consentite dalla legge del tuo paese di residenza. Se ignori questo avviso, Boston Scientific declinerà ogni responsabilità che deriva dall'accesso alle informazioni contenute.

---

https://news.bostonscientific.eu/2014-05-21-Boston-Scientific-Lotus-TM-Valve-System-Demonstrates-Strong-Performance-And-Safety-Profile-At-Six-Months-EN