Boston Scientific Reports Lotus™ Valve System Met Primary Performance Endpoint in REPRISE II Trial

Boston Scientific Corporation (NYSE: BSX) reports positive results from a pre-specified analysis of the first 60 patients enrolled in the REPRISE II trial evaluating the performance and safety of the Lotus™ Valve System in symptomatic patients with severe aortic valve disease considered at high risk for surgical valve replacement. The Lotus Valve System is the first transcatheter aortic valve replacement (TAVR) device of its kind with an Adaptive Seal™ that is designed to minimize aortic regurgitation (leaking), a proven predictor of mortality, and is both fully repositionable and retrievable prior to release. Data were presented today as a late-breaking clinical trial at the EuroPCR Scientific Program in Paris by Professor Ian Meredith, director of MonashHeart, at Monash Medical Centre in Melbourne, Australia, and principal investigator of the REPRISE II trial. The data demonstrated that the Lotus Valve System met the primary performance endpoint for the first 60-patient cohort and was implanted successfully in all patients (60/60 patients) with no case of severe paravalvular regurgitation.

REPRISE II is an ongoing prospective, single-arm study that has completed enrollment of 120 patients at fourteen sites in Australia, France, Germany and the United Kingdom. All patients had severe symptomatic aortic stenosis and were considered at high risk for surgical valve replacement. REPRISE II is being extended to enroll an additional 130 patients at twenty sites in Australia and Europe.

Results

- The primary device performance endpoint was met as the 30-day mean aortic valve pressure gradient of 11.28+5.23 mmHg with a one-sided upper confidence bound of 13.09 was significantly less ($P<0.0001$) than the performance goal of 18 mmHg.
- The primary safety endpoint, defined as all-cause mortality at 30 days, was 1.7 percent.
- Independent core lab assessment of paravalvular aortic regurgitation at 30 days indicated no severe regurgitation and one case of moderate regurgitation (1.9 percent). In 79.2 percent of patients there was trace or no paravalvular regurgitation at 30 days.
- No instances of non-study valve implantation, unplanned use of cardiopulmonary bypass, valve embolization, valve-in-valve or ectopic valve placement occurred.

"The ability to initially position the Lotus valve very precisely and, if needed, to easily reposition or indeed fully retrieve the valve provide the operator with remarkable control," said Professor Meredith. "When combined with immediate and near complete elimination of aortic regurgitation, even in patients who began with moderate or severe aortic regurgitation, the results are impressive and reflect very favorably on the unique features of the Lotus technology."

One-year results from REPRISE I, a prospective, single-arm feasibility study on patients with severe symptomatic aortic stenosis conducted in Australia, were also presented today by Professor Meredith. Data demonstrated sustained safety and performance of the Lotus valve out to one year, with no new major adjudicated events as defined by the Valve Academic Research Consortium (VARC), and no moderate or severe paravalvular aortic regurgitation in any patients.

"The new results from our Lotus trial program, and particularly from REPRISE II, underscore the promising unique technology behind the Lotus Valve System," said Keith Dawkins, M.D., global chief medical officer, Boston Scientific. "These features help to simplify the implantation procedure and may lead to improved clinical outcomes, showing how the Lotus valve can offer a new treatment alternative for patients with severe aortic valve disease considered being at high risk for surgical valve replacement."

The Lotus Valve System is an investigational device worldwide, 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.

The results of the REPRISE trials are expected to be used to support CE mark and other international regulatory approvals.

About the Lotus Valve System
The Lotus Valve System is a differentiated second-generation TAVR technology, which 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.

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.

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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, regulatory approvals, clinical trials and the importance of their results, 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.

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