Boston Scientific Lotus™ Valve System demonstrates strong performance

The Boston Scientific Lotus™ Valve System advanced TAVR technology continued to demonstrate impressive performance at three months, according to new data presented at ACC 2014.

The REPRISE II clinical trial, evaluating the Lotus™ Valve System in symptomatic patients with severe aortic valve stenosis considered at high risk for surgical valve replacement, demonstrated favorable safety and efficacy outcomes out to three months with 85 percent of patients having no paravalvular aortic regurgitation. 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.

REPRISE II is an ongoing prospective, single-arm study that has enrolled 120 patients at 14 sites in Australia, France, Germany and the U.K. An additional 130 patients will be enrolled in an extension of REPRISE II at 16 sites in Australia and Europe, and enrollment in this extension of REPRISE II is expected to be complete in April 2014.

Key findings from the study include the following:

- At 90 days, an impressive 85.4 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 90 days. There were two cases of moderate paravalvular aortic regurgitation (2.1 percent) and in 12.5 percent of patients, paravalvular regurgitation was considered mild.
- The primary device performance endpoint of 30-day mean aortic valve pressure gradient, as assessed by an independent core laboratory, was met as the 30-day mean aortic valve pressure gradient of 11.5±5.2 mm Hg was significantly ($P<0.001$) less than the performance goal of 18 mm Hg. At 90 days, the mean aortic valve pressure gradient remained low and stable at 11.5±5.4 mm Hg.
- All-cause mortality at 90 days was 5 percent.
- No instances of non-study valve implantation, unplanned use of cardiopulmonary bypass, valve embolization, valve-in-valve or ectopic valve placement occurred.
- The disabling stroke rate at 90 days was 2.5 percent.

One-year results from REPRISE I, a prospective, single-arm feasibility study of patients with severe symptomatic aortic stenosis conducted in Australia, were presented in May of 2013 at EuroPCR by Professor Meredith and published online ahead of print by EuroIntervention. The data demonstrated sustained safety and performance of the Lotus™ Valve System out to one year with no moderate or severe paravalvular aortic regurgitation in any patient.

About the Lotus™ Valve System
The Lotus™ Valve System is a differentiated second-generation TAVR 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, 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. 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 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 markets for our products, our business plans, clinical trials, product performance 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.
