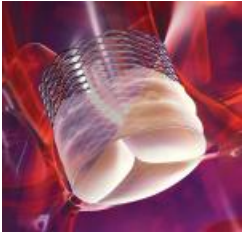


## Boston Scientific Reports Favorable Six-Month Results from Lotus™ Valve System Clinical Trial



*Lotus™ Valve System*

### **BOSTON SCIENTIFIC REPORTS favorable SIX-MONTH RESULTS from LOTUS™ valve system clinical trial**

#### **REPRISE II Data Honored as Best Abstract 2013 at PCR London Valves Course**

Natick, Mass. (Sept. 17, 2013) – Boston Scientific Corporation (NYSE: BSX) reported favorable six-month results from the first 60 patients enrolled in the REPRISE II clinical trial evaluating the safety and performance of the Lotus™ Valve System in symptomatic patients with severe aortic stenosis considered at high risk for surgical valve replacement.

The data, which were presented today at PCR London Valves and formally received the honor of Best Abstract 2013, demonstrated excellent results with no new valve-related adverse events between 30 days and six months. Additionally, there were no cases of moderate or severe paravalvular regurgitation in any patient at six months.

Six-month results:

- Excellent hemodynamic results continue to be observed at six months as demonstrated by mean aortic valve pressure gradient of  $12.1 \pm 5.0$  mmHg and mean aortic valve area of  $1.8 \pm 0.5$  cm<sup>2</sup>.
- Independent core lab assessment of paravalvular aortic regurgitation showed 76.1 percent of patients presenting with no paravalvular regurgitation and no cases of moderate or severe regurgitation.
- There were no new valve-related adverse events recorded between 30 days and six months.
- The NYHA classification data demonstrated a significant improvement in heart failure symptoms at six months compared to baseline.

"The Lotus Valve System provides the operator with superb control allowing precise positioning and accurate deployment," said Professor Ian Meredith, director of MonashHeart at Monash Medical Centre in Melbourne, Australia, and principal investigator of the REPRISE II trial. "The results from the first 60 patients of the REPRISE II trial are very impressive, especially with no patients presenting with moderate or severe paravalvular regurgitation at six months."

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) around the valve, a proven predictor of mortality, and is both fully repositionable and retrievable prior to release.

Boston Scientific expects to release additional REPRISE II data in late October at the TCT (Transcatheter Cardiovascular Therapeutics) conference in San Francisco.

"The latest results from REPRISE II underscore the promising and unique technology behind the Lotus Valve System, demonstrating how the Lotus Valve System can offer a new treatment alternative for patients with severe aortic valve disease," 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."

The Lotus Valve System is an investigational device worldwide and not available for sale. To view and download an image of the Lotus Valve System, [click here](#).

The results of the REPRISE clinical trial program are expected to be used to support CE Mark and other international regulatory approvals.

#### **About REPRISE II**

REPRISE II is an ongoing prospective, single-arm study that has completed enrollment of 120 patients at 14 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. An additional 130 patients are expected to be enrolled at a total of 20 sites in Australia and Europe in an extension of REPRISE II.

## 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](http://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 regulatory approvals, clinical trials, 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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