Boston Scientific

The Boston Scientific LOTUS™ Valve System Demonstrated Superior Efficacy to CoreValve® in Global REPRISE III Trial at One Year

PARIS and MARLBOROUGH, Mass., May 16, 2017 /PRNewswire/ -- Boston Scientific (NYSE: BSX) today announced positive results from the REPRISE III clinical trial, presented at the annual EuroPCR Scientific Program, in Paris. Data from the study demonstrated that the LOTUS™ Valve System*, a transcatheter aortic valve implantation (TAVI) system, showed superiority over the CoreValve® TAVI System platform** for the primary effectiveness endpoint and non-inferiority for the primary safety endpoint.

The primary effectiveness endpoint, a composite of all death, disabling stroke and moderate or greater paravalvular aortic leakage (PVL) at one year, was lower with the LOTUS Valve system compared to the CoreValve platform (16.7% vs. 29.0%, p<0.001). The LOTUS Valve system also demonstrated non-inferiority to CoreValve platform for the primary safety endpoint which was a composite of all-cause mortality, stroke, life-threatening and major bleeding events, stage two or three acute kidney injury or major vascular complications through 30 days.

The pre-specified secondary endpoint demonstrated the LOTUS Valve system had significantly lower rates of moderate to severe PVL occurrences when compared to the CoreValve platform (0.9% vs. 6.9%, p<0.001).***

"The excellent results seen in this large randomized trial, particularly the superior performance in efficacy and the continued demonstration of low PVL rates, further establish the advantages of the LOTUS Valve system," said Ted E. Feldman, M.D., director, Cardiac Catheterization Laboratory, NorthShore University HealthSystem in Evanston, Illinois, and co-investigator of the REPRISE III trial. "With the LOTUS Valve system, I have confidence that I can position the valve accurately in every case and achieve good outcomes for my patients."

REPRISE III is the first head-to-head pivotal study comparing two different TAVI platforms: the LOTUS Valve system and the CoreValve platform, including both CoreValve and EvolutR™. It is a multi-center, randomized controlled trial that included 912 patients from the United States, Europe, Canada and Australia with severe aortic stenosis who were considered to be at high or extreme risk for surgical valve replacement.

"We are very excited by the performance of the LOTUS Valve system in this trial as it represents a crucial piece of clinical evidence for the LOTUS platform," said Ian Meredith, M.D., executive vice president and global chief medical officer, Boston Scientific. "We believe that these data, along with upcoming findings to be shared from the RESPOND and RESPOND Extension studies, can further illustrate the unique clinical benefits that this system offers physicians for the treatment of patients."

* The LOTUS Valve System is not available for sale.
** CoreValve and EvolutR are registered trademarks of Medtronic.
*** Revised on September 9, 2017, to reflect updated data for the occurrence of moderate or greater PVL. The original press release cited 2.0% for the LOTUS Valve system and 11.1% for the CoreValve platform.

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 of the valve, resulting in restricted 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.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 clinical trials, product launches and product performance and impact. 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; the closing and integration of acquisitions; 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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