Boston Scientific

Boston Scientific Announces Update on LOTUS Edge™ Aortic Valve System

MARLBOROUGH, Mass., Nov. 28, 2017 /PRNewswire/ -- Boston Scientific (NYSE: BSX) announces a delay to previously communicated timelines for commercialization of the LOTUS Edge™ Aortic Valve System* in Europe and the U.S.

After initiating a voluntary recall for the LOTUS and LOTUS Edge Aortic Valve Systems earlier this year, Boston Scientific implemented manufacturing process and design specification changes to the LOTUS Edge delivery system with the intent of re-introducing the product in Europe by the first quarter of 2018 and filing the final Pre-Market Approval (PMA) module with the U.S. Food and Drug Administration by January 2018.

The company now expects to provide an update on the status of the LOTUS Edge Valve during its fourth quarter 2017 earnings conference call on February 1, 2018, as it continues to focus on manufacturing and regulatory milestones to support the long-term success of the Lotus platform.

"We continue to see value in the unique benefits of the LOTUS Valve platform in treating patients with aortic stenosis," said Mike Mahoney, chairman and chief executive officer, Boston Scientific. "While we are disappointed in this delay to our timelines, we are working to carefully analyze and implement necessary modifications to pass our rigorous internal quality standards."

Boston Scientific will continue to work closely with the U.S. and European regulatory bodies to share pertinent updates about these delays and impact to submission timing.

Today's announcement is not expected to have a material financial impact to Boston Scientific fourth quarter or full year 2017 guidance.

Conference Call and Webcast Information
Boston Scientific will be hosting a conference call for investors on Wednesday, November 29, at 8:30 a.m. EST to discuss the announcement. To participate in the conference call, please dial (800) 230-1096 or (612) 234-9959. The live webcast and archived replay of this call will be available at our Investor Relations website investors.bostonscientific.com in the Events section.

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.

*The LOTUS Valve System is not available for sale.

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 our business plans, expectations with respect to the Lotus Valve System, 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; 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.

CONTACTS:
Kelly Leadem
Media Relations
(508) 683-5543 (office)
Kelly.Leadem@bsci.com

Susie Lisa, CFA
Investor Relations
(508) 683-5565 (office)
investor_relations@bsci.com

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