Boston Scientific announces CE mark and FDA clearance for the Safari2™ Pre-Shaped Guidewire

First Guidewire Designed Specifically for TAVI/R Now Sized for Smaller Ventricles

Boston Scientific (NYSE: BSX) announces CE Mark and FDA clearance for the Safari2™ Pre-Shaped Guidewire, a new and enhanced version of the Safari Guidewire, intended to facilitate the introduction and placement of interventional devices within the heart, including those used with transcatheter aortic valve implantation or replacement procedures (TAVI/R). The Safari2 Guidewire is compatible for use with all TAVI/R devices.

The Safari2 Guidewire provides a streamlined device delivery with enhanced wire predictability and shape retention for interventional devices within the heart. Additionally, the Safari2 product line offers the widest guidewire choice with three curve sizes, including a new extra small curve designed for procedures involving patients with smaller ventricles, a current unmet need in this population.

“Having a pre-shaped, universal TAVR guidewire helps physicians deliver the replacement valve with reliability and consistency,” said Wesley Pederson, M.D., director of Valve and Structural Heart Disease at the Minneapolis Heart Institute. “This is a wonderful development to have a smaller curve size so that we can offer this less invasive treatment option to a broader range of patients because valvular disease can have a devastating impact on patient survival and quality of life.”

Prior to the introduction of the Safari Guidewire, physicians could only use peripheral intervention guidewires manually shaped for TAVI/R procedures. Safari was the first pre-shaped, TAVI/R guidewire on the market designed specifically to be used within the chambers of the heart. View or download an image of the Safari² Guidewire.

“The Safari2 Guidewire reflects our dedication and our commitment to meaningful innovation in the treatment of structural heart disorders,” said Tom Fleming, vice president and general manager, Structural Heart, Boston Scientific. “We will continue to invest in technologies like Safari2 which facilitate successful TAVI/R outcomes and improve quality of life for patients with valvular disease worldwide.”

The Safari2 Guidewire complements the Boston Scientific Lotus™ Valve System, a next-generation TAVI/R device designed to give physicians more control throughout the TAVI/R procedure. The Lotus Valve System received CE Mark approval in October of 2013 and offers a unique alternative treatment for patients with severe aortic stenosis and who are at high risk for surgical valve replacement. In the U.S., the REPRISE III pivotal clinical trial began enrolling patients last year and is designed to evaluate the safety and effectiveness of the Lotus Valve System. As such, the Lotus Valve System is an investigational device in the U.S. and not available for sale. The Safari2 Guidewire and the Lotus Valve System are distributed separately.

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.eu 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 our business plans, regulatory approvals, clinical trials, 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.

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