Boston Scientific

Boston Scientific Announces U.S. FDA Approval of Navigation-Enabled Ablation Catheters

New catheters and software enhancement expand capabilities of high-definition Rhythmia™ Mapping System

MARLBOROUGH, Mass., May 3, 2016 /PRNewswire/ -- Boston Scientific (NYSE: BSX) has received U.S. Food and Drug Administration (FDA) approval for two catheters that can be used with the Rhythmia™ Mapping System. The IntellaNav™ XP and the IntellaNav MiFi™ XP navigation-enabled ablation catheters – designed to map and ablate – were approved to treat Type I atrial flutter, an abnormal rhythm of the upper chambers of the heart. These are the first magnetically-tracked catheters that Boston Scientific will offer to the U.S. market. Along with the immediate launch of the catheters, the company is also releasing a software enhancement for the Rhythmia Mapping System.

"By combining these new magnetic navigation-enabled catheters with our high-density, high-resolution Rhythmia Mapping System, we can create enhanced maps that help diagnose arrhythmias and improve guidance during cardiac ablation procedures," said Kenneth Stein, M.D., chief medical officer, Rhythm Management, Boston Scientific. "With these approvals, we continue the expansion of our electrophysiology product offerings, further demonstrating our commitment to help electrophysiologists provide the highest quality of care for their patients."

Unlike conventional cardiac mapping systems, the Rhythmia Mapping System rapidly and automatically generates three-dimensional images of any chamber of the heart to help diagnose, locate and treat the source of rhythm abnormality. The Software Version 1.4 mapping system update improves the speed and quality in which the images are acquired using a variety of therapeutic and diagnostic catheters, including the IntellaNav XP and IntellaNav MiFi XP catheters. The software update also provides advanced editing capabilities, allowing for detailed visual enhancements of the maps.

Both of the newly approved IntellaNav XP catheters feature magnetic sensors which track the location of the catheter while delivering radiofrequency energy into the heart muscle, creating heat to destroy a small area of the tissue responsible for the abnormal heart rhythm. The IntellaNav MiFi XP catheter also provides increased accuracy and signal clarity via mini-electrode technology which delivers a highly localized signal closely reflecting what is happening at the tip in real-time during the ablation procedure.

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 our business plans and regulatory approvals. 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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