Boston Scientific announces FDA and CE Mark Approval Of The EMBLEM™ S-ICD System

Innovative device offers first-line treatment for patients at risk of sudden cardiac arrest

MARLBOROUGH, Mass., March 17, 2015 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has received FDA and CE Mark approval of the EMBLEM™ Subcutaneous Implantable Defibrillator (S-ICD) System. The EMBLEM S-ICD System is a treatment option that provides protection for patients at risk of sudden cardiac arrest (SCA), yet leaves the heart and vasculature untouched, minimizing the risk of complications associated with conventional transvenous implantable cardioverter-defibrillators (TV-ICDs). A controlled and limited market release has begun in a small number of European centers with a broad European launch scheduled for May 2015 and subsequent U.S. launch planned for the third quarter of 2015.

"We are excited to offer the second generation S-ICD System to physicians as a compelling treatment option for the majority of ICD-indicated patients," said Kenneth Stein, M.D., Chief Medical Officer, Rhythm Management, Boston Scientific. "With the already established robust safety and efficacy clinical data, the EMBLEM S-ICD System is designed to enhance patient comfort, while still providing a less invasive treatment for patients at risk of cardiac arrest."

Unlike traditional ICDs that require placement of at least one lead in or on the heart, the S-ICD System is implanted just under the skin and provides the patient the same protection from cardiac arrest without invading the heart and blood vessels. Leads in the heart may be associated with infrequent but serious complications, including lead displacement, fracture and systemic blood infections, or the need for lead extraction, which may lead to hospital readmission, increased mortality and associated costs.

The new generation EMBLEM S-ICD System is 20% thinner and is projected to last 40% longer than the previous S-ICD System. These improvements will further improve patient comfort and cosmetic outcomes while reducing the number of times the device will require replacement. The EMBLEM S-ICD System is also enabled for remote patient management through the LATITUDE™ NXT Patient Management System for increased patient convenience.

"We are further strengthening our range of therapeutic solutions to protect patients from sudden cardiac arrest," said Joe Fitzgerald, executive vice president and president of Rhythm Management at Boston Scientific. "Boston Scientific is the first and only company to offer a fully subcutaneous ICD, and we expect to maintain leadership in this category through continued investment in technology and clinical science. We are very pleased with this earlier than expected FDA approval, and will immediately begin preparations for a mid-year launch of the EMBLEM device in the US."

For more information on the S-ICD System visit www.sicdsystem.com.

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 us at www.bostonscientific.com. For more information, visit us at www.bostonscientific.com or connect with us on Twitter or 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 new product launches and launch cadence, regulatory approvals, clinical trials, product performance 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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