Boston Scientific

Boston Scientific Announces Positive Long-Term Outcomes For S-ICD System In The EFFORTLESS Study

Late-Breaker Data Presented at HRS Scientific Sessions Is Most Extensive Post-Market Study for S-ICD

SAN FRANCISCO and MARLBOROUGH, Mass., May 6, 2016 /PRNewswire/ -- Boston Scientific (NYSE: BSX) today announced results from the largest post-market registry for the Subcutaneous Implantable Defibrillator (S-ICD) System. Data collected from the EFFORTLESS study were presented as a late-breaking clinical trial at the 37th Annual Scientific Sessions of the Heart Rhythm Society (HRS) in San Francisco, and confirmed long-term safety and efficacy for the only device available to treat sudden cardiac arrest without leads touching the heart and vasculature.

The multi-national registry included 985 patients who were observed for up to five years post-implant – more than any S-ICD data the company has previously published. Primary results demonstrate low complication rates associated with the S-ICD device, with a complication-free rate of 99.7% at 30 days, and 98.0% at 360 days post-procedure.

"We have long believed in the value of eliminating unnecessary patient complications by choosing a defibrillator which does not require intracardiac leads," said Lucas V. A. Boersma, M.D., Ph.D., electrophysiologist at St. Antonius Hospital,The Netherlands. "This post-approval registry further confirms that not only is the Subcutaneous Implantable Defibrillator an effective therapy, but its benefits are consistent amongst the full range of indicated patient subsets."

The efficacy of the S-ICD System was further validated in this analysis, with a 97.4% conversion rate of discrete arrhythmias that can lead to sudden death.

Follow-up at an average 3.1 years revealed that few S-ICDs were removed due to a change of patient indication. Only five (0.5%) S-ICDs were removed in order to implant a patient with a defibrillator with anti-tachycardia pacing (ATP) capabilities, and only one (0.1%) was removed to allow for a device with bradycardia pacing capabilities.

"We are building on the success we've seen with the S-ICD system by exploring a modular therapy approach that keeps the vasculature untouched," said Kenneth Stein, M.D., chief medical officer, Rhythm Management, Boston Scientific. "We are developing the EMPOWER™ Modular Pacing System, which includes our leadless pacemaker and the EMBLEM™ S-ICD System. Whether patients with life-threatening arrhythmias subsequently develop a need for pacing or vice versa, we are designing this modular solution to enable electrophysiologists to treat patients with the therapies they need, when they need them."

Since receiving CE Mark and U.S. Food and Drug Administration approval for the S-ICD System in 2009 and 2012, respectively, Boston Scientific launched a next generation EMBLEM S-ICD System which is 20% thinner and is projected to last 40% longer than the original S-ICD System. Last month, the company was granted CE Mark for the new EMBLEM MRI S-ICD System as well as magnetic resonance conditional labeling for all previously implanted EMBLEM S-ICD Systems, meaning the devices are considered safe for use in a magnetic resonance image setting when conditions of use are met.

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

In the U.S., the EMBLEM MRI S-ICD System and EMPOWER Modular Pacing System are not available for use or sale.

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 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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