Boston Scientific

Long-Term Data Underscore Safety And Efficacy Of The Boston Scientific S-ICD™ System

Results Published in the Journal of American College of Cardiology

MARLBOROUGH, Mass., April 20, 2015 /PRNewswire/ -- Today the *Journal of the American College of Cardiology* published data confirming the long-term safety and efficacy of the Boston Scientific Corporation (NYSE: BSX) S-ICD System™ (subcutaneous implantable defibrillator) for patients at risk of sudden cardiac arrest.

The study, "Safety and Efficacy of the Totally Subcutaneous Implantable Defibrillator: 2-year Results from a Pooled Analysis of the IDE Study and EFFORTLESS Registry" was led by Dr. Martin Burke, professor of medicine at the University of Chicago. The analysis combined data from two large S-ICD studies to provide the most comprehensive look at S-ICD System patient outcomes to date.

The S-ICD System – which was approved by the Food & Drug Administration (FDA) in 2012 and which gained Category 1 CPT Codes in January – was shown to be highly effective, converting more than 98 percent of heart arrhythmias that can lead to sudden death. These data are comparable to efficacy outcomes found in transvenous ICD (TV-ICD) clinical trials (95-99%)[1-4].

When assessing 889 patients with a total of 1,571 patient-years of follow-up, there were no lead failures and no systemic infections associated with the S-ICD System. The total rate of complications observed in this analysis was low relative to rates found in comparable TV-ICD studies[5,6]. The rate of cumulative complications increased by just one percentage point annually after the first year (9% at one year; 10% at two years; 11% at three years). Major acute complications related to the operation were lower than observed in studies with TV-ICD (2% [i] versus 3-5%)[7,8].

"The S-ICD device sits just below the skin without the need for electrodes or leads to be placed into the heart and so it makes sense that we see decreased serious complications," said Dr. Burke. "By using the S-ICD System we can avoid the key risks that cause systemic or endovascular infections, which can add weeks to a hospital stay, incur tens of thousands of dollars in incremental hospital costs, and which are also associated with mortality for up to one-third of TV-ICD patients who acquire this type of infection."

The all-cause mortality rate for the S-ICD patients was 1.6 percent per year, comparing favorably to observed mortality rates in similar TV-ICD studies (2.5-5.5% per year)[9-11].

This study combined data from the U.S. Investigational Device Exemption study that led to the device's approval by the FDA and also data from the EFFORTLESS registry, each with extended follow-up (average 22 months) relative to previously published reports on the S-ICD System.

Currently, the S-ICD System is covered nationally by Medicare, Aetna, Cigna and others, and regionally by numerous private and Medicaid plans, providing coverage for approximately 170 million individuals in the U.S.

The S-ICD System has been commercially available in Europe since 2009. For more information on the S-ICD system, please visit www.bostonscientific.com/sicd.

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 product launches and launch cadence, clinical trials and impact of data, product performance and impact, 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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[i] S-ICD complications included hematoma and lead/device mal-positioning/displacement

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