Boston Scientific

Largest Randomized Clinical Trial Of Implantable Cardioverter Defibrillator Recipients Demonstrates Excellent Patient Outcomes With Or Without Defibrillation Testing

NATICK, Mass., May 8, 2014 /PRNewswire/ -- A Boston Scientific Corporation (NYSE: BSX) study demonstrated that outcomes for patients with the company's transvenous implantable cardioverter defibrillators (ICD) who received routine defibrillation testing (DT) at implant were similar to outcomes for those patients who did not receive defibrillation testing. The **S**hockless **IMPL**ant **E**valuation (SIMPLE) study is the largest randomized clinical trial of ICD recipients to date. The primary results were presented at the Heart Rhythm Society's 35th Annual Scientific Sessions in San Francisco by Jeff S. Healey, M.D., FRCPC, associate professor, Division of Cardiology and the Department of Medicine at McMaster University, Ontario, Canada.

The trial results demonstrated that routine defibrillation testing at the time of ICD implant was safe, but did not improve shock efficacy or reduce mortality compared to the no-testing strategy. Specifically, the investigators demonstrated non-inferiority for the primary endpoint of ineffective clinical shock or arrhythmic death (7.22% in the no-DT group vs. 8.30% in the DT group ($P_{Noninferiority}$=0.0001)). The rate of survival from arrhythmic death was 94.8% in the no-DT group vs. 94.4% in the routine DT group (P=0.50). The primary safety endpoint, comprised of complications within 30 days of the implant, was also similar between the two patient groups (5.4% in the no-DT group vs. 6.5% in the routine DT group, p=0.25). Thus, despite questions regarding the need for routine defibrillation testing, it is generally safe and may still be suitable for certain patients at the physician's discretion.

"Defibrillation testing has long been a standard practice among electrophysiologists, but there has been little evidence suggesting it improves outcomes," said Jeff S. Healey, M.D., FRCPC, associate professor, Division of Cardiology and the Department of Medicine at McMaster University, Ontario, Canada. "Our findings from the SIMPLE study demonstrate that those patients who received ICDs without defibrillation testing did as well as those who underwent the standard defibrillation testing at the time of implant."

This study of Boston Scientific ICDs also demonstrated excellent efficacy in the secondary endpoint of first shock efficacy. The rate of 91 percent for first shock efficacy in the no-DT group was comparable to the findings in landmark ICD studies, such as SCD-HeFT (83 percent), as well as in the recently reported S-ICD™ System EFFORTLESS registry (88 percent).

"We are proud to have exclusively sponsored the investigators in the largest randomized trial of ICD recipients to date, and are now able to address a key clinical question that has been debated since we pioneered ICD therapy 30 years ago," said Kenneth Stein, M.D., chief medical officer, Rhythm Management, Boston Scientific. "While the study challenges the value of routine defibrillation testing, physicians and their patients should be comforted by the safety and efficacy of our ICD devices with either approach."

ICDs are designed to provide protection to patients at risk of sudden cardiac death (SCD). Sudden cardiac death is a sudden, unexpected death caused by loss of heart function and is a leading cause of death. Nearly 400,000 out-of-hospital cardiac arrests occur annually in the United States.[i]

The SIMPLE trial randomized 2,500 ICD recipients in 18 countries to groups either receiving or not receiving defibrillation testing, a method to test the ability of the ICD to treat an induced ventricular fibrillation during the implant procedure. Defibrillators with cardiac resynchronization therapy (CRT-D), which treat asynchronous heart beats common in heart failure patients, were also included. Average follow-up was over 3.1 years.

Boston Scientific offers the world's only subcutaneous ICD, the world's smallest, thinnest ICDs, as well as ICDs and CRT-Ds with nearly double the battery capacity of some competitive products, to improve patient outcomes and cost effectiveness.

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 30 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 markets for our products, 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

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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] American Heart Association, "Heart Attack or Sudden Cardiac Arrest: How Are They Different?"; content accessed 5/6/2014.

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