Boston Scientific

Boston Scientific Announces Real-World Data Demonstrating Success Of SMART Pass On The S-ICD System

Late-Breaker Data Highlight Reduction in Rate of Inappropriate Shocks with Sensing Filter

MARLBOROUGH, Mass., May 11, 2018 /PRNewswire/ -- Boston Scientific (NYSE: BSX) today announced results from an analysis of the LATITUDE database which evaluated the successful reduction of inappropriate shocks using the SMART Pass sensing filter in patients implanted with the EMBLEM™ Subcutaneous Implantable Defibrillator (S-ICD) System. The real-world data were presented during a late-breaking clinical trial at Heart Rhythm 2018, the Heart Rhythm Society's 39th Annual Scientific Sessions in Boston, and demonstrated that when the sensing filter was in use, the rate of inappropriate shocks was reduced to 4.3% at one year. The analysis was also published online today in the *Heart Rhythm Journal*.

The SMART Pass sensing filter is an advanced algorithm within the EMBLEM S-ICD System that filters out certain signals that are the primary reason for inappropriate shocks, while maintaining the ability to accurately detect ventricular tachycardia or ventricular fibrillation and deliver lifesaving therapy. Study authors evaluated the effect of SMART Pass on shocks in ambulatory patients and found that the filter reduced the risk for the first inappropriate shock by 50% and the risk for all inappropriate shocks by 68%, without a negative impact on delivery of appropriate shocks.

"The study data validate the clinical benefit of this sensing methodology to significantly reduce inappropriate shocks by the S-ICD," said Tom F. Brouwer, M.D., presenting author, Department of Clinical and Experimental Cardiology, Academic Medical Center, University of Amsterdam, The Netherlands. "At one year, the inappropriate shock rate for patients with the SMART Pass filter in use was as low as rates observed in studies with transvenous implantable cardioverter-defibrillators employing modern programming strategies."

The prospective, blinded evaluation reviewed one year of remote monitoring data from 1,984 patients that were implanted with an EMBLEM S-ICD System between 2015 and 2016.

"The positive data presented today underscore our commitment to advancing this device and providing protection for patients at risk for sudden cardiac death while avoiding the risks and complications associated with transvenous leads," said Kenneth Stein, M.D., senior vice president and chief medical officer, Global Health Policy and Rhythm Management, Boston Scientific. "We are excited for the future of the S-ICD and results from upcoming clinical trials assessing its value when paired with our forthcoming leadless pacemaker as part of a modular device system."

The S-ICD was included for the first time in the recently updated guidelines from the American Heart Association (AHA), the American College of Cardiology (ACC) and the Heart Rhythm Society (HRS) which recommend the device for the treatment of patients with ventricular arrhythmias and the prevention of sudden cardiac death.[1]

For more information on the EMBLEM MRI S-ICD System visitwww.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 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, clinical trials 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.

CONTACTS:

Laura Aumann
Media Relations
(651) 582-4251 (office)
Laura.Aumann@bsci.com

Susie Lisa, CFA
Investor Relations
(508) 683-5565 (office)
BSXInvestorRelations@bsci.com

[1] Al-Khatib SM, Stevenson WG, Ackerman MJ, Bryant WJ, Callans DJ, Curtis AB, Deal BJ, Dickfeld T, Field ME, Fonarow GC, Gillis AM, Hlatky MA, Granger CB, Hammill SC, Joglar JA, Kay GN, Matlock DD, Myerburg RJ, Page RL, 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death, *Heart Rhythm* (2017), doi: 10.1016/j.hrthm.2017.10.036.

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https://news.bostonscientific.com/2018-05-11-Boston-Scientific-Announces-Real-World-Data-Demonstrating-Success-Of-SMART-Pass-On-The-S-ICD-System