Boston Scientific

Boston Scientific S-ICD System Demonstrates Positive Clinical Outcomes in the Largest Prospective Study of 'Real-World' Patients

Late-Breaker Data Presented at Heart Rhythm 2017

MARLBOROUGH, Mass., May 11, 2017 /PRNewswire/ -- Boston Scientific (NYSE: BSX) today announced results from the U.S. post-market approval study evaluating 'real-world' patients implanted with the Subcutaneous Implantable Defibrillator (S-ICD) System, the largest S-ICD study to date. Data collected from the study were presented during a late-breaking clinical trial at Heart Rhythm 2017, the Heart Rhythm Society's 38th Annual Scientific Sessions in Chicago, and demonstrated that physicians are implanting the S-ICD System largely for patients typically treated with transvenous implantable cardioverter defibrillators (TV-ICD) as well as for sicker patients while achieving a high success rate and low complication rate.

Acute results demonstrate the therapy effectively terminated life-threatening heart arrhythmias in 98.7 percent of evaluated patients. The S-ICD System analysis also validated low complication rates, with a complication-free rate of 96.2 percent at 30 days post-procedure.

"The 'real-world' population enrolled in the largest S-ICD study to date demonstrates that the device has low complication rates and very high success rates for terminating ventricular fibrillation, thereby serving as an alternative treatment to transvenous ICDs," said Michael R. Gold, M.D., Ph.D, U.S. principal investigator and Michael E. Assey professor of medicine at The Medical University of South Carolina, Charleston. "The population studied here is more similar to transvenous ICD populations compared to previous S-ICD studies, reinforcing this device can be used in a broad population of ICD-indicated patients."

The non-randomized registry, initiated in 2012 after the S-ICD System received U.S. Food and Drug Administration approval, included 1,637 patients implanted with the device at 86 U.S. medical centers. Nearly two-thirds of the patients evaluated in the study were primary prevention patients with a low ejection fraction, which represents the highest proportion of patients that are implanted with ICD devices. Additionally, more than half of the patients had comorbidities such as heart failure and hypertension, and more than 13 percent were on dialysis for end stage renal disease.

"Beyond the positive clinical outcomes, we are also seeing advancements in procedural techniques as physician experience and confidence continue to build," said Kenneth Stein, M.D., senior vice president and chief medical officer, Global Health Policy and Rhythm Management, Boston Scientific. "Physicians are implanting over half of the devices with two surgical incisions rather than the standard three incisions and avoiding use of general anesthesia in more than one-third of patients."

To further develop the clinical body of evidence in support of the S-ICD System, Boston Scientific initiated a worldwide study called the Multicenter Automatic Defibrillator Implantation Trial with Subcutaneous Implantable Cardioverter Defibrillator (MADIT S-ICD) last month. The study will evaluate the survival benefit of patients treated with the EMBLEM™ MRI S-ICD System – the latest generation S-ICD system – who are aged 65 and older with a history of prior heart attack, diabetes and moderately reduced left ventricular ejection fraction.

For more information on the EMBLEM MRI 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 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:
Trish Backes
Media Relations
(651) 582-5887 (office)
Trish.Backes@bsci.com

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

SOURCE Boston Scientific

---

https://news.bostonscientific.com/2017-05-11-Boston-Scientific-S-ICD-System-Demonstrates-Positive-Clinical-Outcomes-in-the-Largest-Prospective-Study-of-Real-World-Patients