Boston Scientific

New Data Illustrate Long-Term Safety And Effectiveness Of The Boston Scientific S-ICD™ System

Interim results of the EFFORTLESS registry published in the European Heart Journal

NATICK, Mass., April 1, 2014 /PRNewswire/ -- Real-world data on the Boston Scientific Corporation (NYSE:BSX) S-ICD System (Subcutaneous Implantable Defibrillator) are highlighted online this week in the European Heart Journal. The interim analysis of the ongoing EFFORTLESS S-ICD registry, which evaluated 456 patients with a mean follow-up of 558 days, is the first real world study to date and confirms the clinical benefits of the S-ICD System in a broad range of patients at risk of sudden cardiac arrest. As the world's least invasive implantable defibrillator, the S-ICD System provides protection for patients at risk of sudden cardiac arrest without touching the heart.

"This data set is important as it is the first long-term real world experience demonstrating safe and effective performance of the S-ICD System," said Pier Liambase, Consultant Electrophysiologist at the Heart Hospital in London, England and lead author of the publication. "This should further establish the S-ICD System as a worthwhile option for a considerable portion of the ICD indicated population that is eligible for the S-ICD System."

The EFFORTLESS registry is a post-market, observational, non-randomized study currently enrolling patients in seven countries, comprised of the Czech Republic, Denmark, Germany, Italy, the Netherlands, New Zealand and the United Kingdom. The registry is expected to enroll 1,000 patients and generate five years of follow-up data.

The publication includes the following highlighted S-ICD System interim results:

- Largest patient cohort (456 patients) with longest follow-up (average of 558 days)
- 100 percent conversion of spontaneous ventricular tachyarrhythmias
- 99.7 percent conversion of acute ventricular tachyarrhythmias
- 6.4 percent inappropriate therapy rate with the use of dual zone programming
- 180- and 360-day complication-free rates of 94 percent

"The EFFORTLESS registry publication provides even more supportive evidence for this innovative therapy. These long-term results in a large patient cohort are comparable to similar data for transvenous ICDs and should help physicians as they decide which patients are the best candidates for the S-ICD System," said Kenneth Stein, M.D., chief medical officer, Rhythm Management, Boston Scientific.

This breakthrough defibrillation therapy has been commercially available in Europe since 2009 and was approved in the United States in late 2012. Boston Scientific continues to expand the availability of this unique therapy for patients and physicians around the world.

The safety and effectiveness of the S-ICD System has not been established in pediatric patients.

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.

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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.

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