Boston Scientific

# Late-Breaking Trial Data Highlight Continued Clinical Success Of Boston Scientific EMBLEM™ S-ICD System

**New data further support use of S-ICD System as first-line therapy for majority of ICD patients**

SAN FRANCISCO and MARLBOROUGH, Mass., May 10, 2019 /PRNewswire/ -- Boston Scientific (NYSE: BSX) today announced acute results from the UNTOUCHED study evaluating safety and efficacy of the EMBLEM™ Subcutaneous Implantable Defibrillator (S-ICD) System for primary prevention of sudden cardiac death specifically in patients with a left ventricular ejection fraction (LVEF) ≤35%, the most common population to be indicated for ICD therapy.[1,2] The data were presented during a late-breaking clinical trial at Heart Rhythm 2019, the Heart Rhythm Society's 40th Annual Scientific Sessions in San Francisco, and demonstrated S-ICD therapy had a complication-free rate of 95.8% at 30 days post-procedure and high conversion efficacy (99.2%) of induced ventricular fibrillation, rates comparable to those seen in previous S-ICD and transvenous implantable cardioverter-defibrillator (TV-ICD) studies. The analysis was also published online today in the *Heart Rhythm Journal*.

The UNTOUCHED study authors also reviewed procedure techniques and 30-day outcomes in patients implanted with the EMBLEM S-ICD System and found that the majority (69%) of procedures were performed using a two-incision technique. The two-incision technique data demonstrated a mean implant time of 55.8 minutes, which was 8 minutes faster than the mean 63.8 minutes for procedures that leveraged a three-incision implant technique, with comparable complication and conversion success rates.

"We found that the complication rate within this primary prevention population was as low as in prior S-ICD registries, despite the patients having much lower LVEF, more hypertension, and diabetes – underscoring that sicker patients do well with this device for the prevention of sudden death," said Lucas V.A. Boersma, M.D., Ph.D., study principal investigator and electrophysiologist at St. Antonius Hospital, the Netherlands. "These acute outcomes also validate the advantages of the two-incision implant technique, which has continued to gain worldwide adoption in the last few years."

The global, prospective, non-randomized study evaluated data from 1,116 patients with a low LVEF, the majority of whom (54%) had ischemic heart disease.

"The data presented today reiterate the value of the EMBLEM S-ICD System for a broad group of ICD-indicated patients, enabling them to avoid the long-term complications associated with TV-ICD leads," said Kenneth Stein, M.D., senior vice president and chief medical officer, Global Health Policy and Rhythm Management, Boston Scientific. "We remain proud of the clinical success of the S-ICD System, which has now been implanted in nearly 60,000 patients worldwide, and we will continue to invest in clinical studies that advance our understanding of the role of the device in patients at risk of sudden cardiac death."

The final results of the UNTOUCHED study, including an analysis comparing inappropriate shock rates of the S-ICD to rates found in previous TV-ICD studies, will be reported after 18-months of patient follow-up.

For more information on the EMBLEM 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 40 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.

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