Boston Scientific

Boston Scientific Initiates Global Study To Assess Sudden Cardiac Arrest Prevention Therapy In Patients With Diabetes Who Have Previously Experienced A Heart Attack

MADIT S-ICD Trial to Study EMBLEM™ MRI Subcutaneous Implantable Defibrillator (S-ICD) System; Trial Recruitment Part of Pilot Initiative to Increase Percentage of Females Enrolled in Clinical Studies

MARLBOROUGH, Mass., April 18, 2017 /PRNewswire/ -- Boston Scientific (NYSE: BSX) has initiated a worldwide study that will evaluate the survival benefit of patients treated with the EMBLEM™ MRI Subcutaneous Implantable Defibrillator (S-ICD) System who are aged 65 and older with a history of prior heart attack, diabetes and moderately reduced left ventricular ejection fraction. This subset of patients is at increased risk for sudden cardiac arrest (SCA), but not currently considered guideline-appropriate candidates for implantable cardiac defibrillators.

This week, the first patient was enrolled in the Multicenter Automatic Defibrillator Implantation Trial with Subcutaneous Implantable Cardioverter Defibrillator (MADIT S-ICD) study by Dr. Michael Giudici, principal investigator and director of Arrhythmia Services at University of Iowa Hospitals and Clinics. The trial is intended to determine if the EMBLEM MRI S-ICD System improves survival as compared to patients remaining on their current medical therapy. The device is a treatment option for patients at risk of SCA that leaves the heart and vasculature untouched, thereby reducing the risk of some complications associated with transvenous implantable cardioverter defibrillators. Eliminating device leads within the vasculature is particularly important for patients with diabetes who often are at an increased risk of infection and vascular access issues.

"Our hypothesis is that the S-ICD device may reduce all-cause mortality in this high-risk cohort of cardiac patients with diabetes," said Dr. Valentina Kutyifa, principal investigator and research assistant professor of cardiology at theUniversity of Rochester Medical Center. "The value of eliminating unnecessary patient complications by implanting a defibrillator which does not require intracardiac leads was an important factor in our decision to utilize the S-ICD device when designing this trial."

The prospective, randomized, multicenter MADIT S-ICD trial will enroll up to 1,800 patients at approximately 100 sites worldwide and is designed as one of two clinical studies piloting the company's WIN-Her™ Initiative which aims to ensure adequate representation of women in clinical trials. Between 2000 and 2007, the average number of women enrolled in U.S. cardiovascular device clinical trials was only one-third of the total study populations.[1] The WIN-Her Initiative will provide recruiting materials customized for women participating at U.S. sites in an effort to increase the number of female enrollees.

"In addition to the knowledge we hope to gain from this population of patients with diabetes, we are excited for the opportunity to improve the broad applicability of the MADIT S-ICD trial results by increasing the enrollment of women in this study," said Kenneth Stein, M.D., senior vice president and chief medical officer, Global Health Policy and Rhythm Management, Boston Scientific. "Moreover, the trial emphasizes our continued commitment to expanding access to all patients who may benefit from this proven technology."

The EMBLEM MRI S-ICD System has been accepted for parallel review for a new indication by the U.S. Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services. The two organizations will concurrently review the MADIT S-ICD trial data as well as other relevant information to determine FDA approval and Medicare coverage of the device for patients 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 visitwww.bostonscientific.com/sicd.

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, regulatory approvals 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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[1] Dhruva SS, Bero LA, Redberg RF. Gender bias in studies for Food and Drug Administration premarket approval of cardiovascular devices. *Circ Cardiovasc Qual Outcomes*. 2011;4(2):165-171.

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