Boston Scientific

Boston Scientific Initiates Global Study To Assess EMBLEM™ Subcutaneous Implantable Defibrillator (S-ICD) In Primary Prevention Patients With Low Ejection Fraction

MARLBOROUGH, Mass., June 22, 2015 /PRNewswire/ -- Boston Scientific (NYSE: BSX) has initiated a worldwide study to evaluate the rate and causes of shocks for patients implanted with the EMBLEM™ Subcutaneous Implantable Defibrillator (S-ICD) for primary prevention of sudden cardiac death in the setting of severely reduced cardiac function (left ventricular ejection fraction </= 35 percent). Primary prevention patients do not have a previously documented life-threatening arrhythmic event, but are at risk of sudden cardiac death and thereby indicated to receive an implantable defibrillator. This group of patients represents the highest proportion of patients that are implanted with transvenous ICD (TV-ICDs) devices today in the United States (U.S.) and European Union (EU).

In order to further demonstrate the usefulness of the S-ICD System in this particular patient population, the UNTOUCHED study will compare outcomes during an 18-month follow-up period to objective performance criteria derived from the Multicenter Automatic Defibrillator Implantation Trial-Reduce Inappropriate Therapy (MADIT-RIT) study. The landmark MADIT-RIT study evaluated shock rates in 1,500 patients implanted with TV-ICD devices and is one of the largest randomized trials to assess shock reduction strategies for TV-ICD devices.[i]

"The MADIT-RIT trial demonstrated that standardized programming using higher rate cutoffs and longer delays to therapy reduces the incidence of inappropriate shocks for TV-ICDs," said Dr. Lucas Boersma, EU principal investigator and electrophysiologist at St. Antonius Hospital, The Netherlands. "The UNTOUCHED trial will examine the incidence of all-cause shocks when using the EMBLEM S-ICD System with standardized therapy settings similar to MADIT-RIT."

The first patient enrolled in the global, multi-site, prospective, non-randomized study received an EMBLEM S-ICD System implant by Dr. Craig Barr, cardiologist at Russells Hall Hospital in Dudley, England. The study will enroll a minimum of 2,015 patients at up to 200 sites worldwide. Enrollments in the U.S. will begin later this summer.

"In the published data to date, we have observed S-ICD devices demonstrate comparable inappropriate shock rates for arrhythmias to TV-ICDs," said Michael Gold, M.D., Ph.D., U.S. principal investigator and chief of cardiology and the Michael E. Assey professor of medicine at Medical University of South Carolina, Charleston. "Ideally, this trial will demonstrate S-ICD devices can either meet or improve upon the inappropriate shock rates experiences with TV-ICDs in MADIT-RIT within this large patient population."

The EMBLEM S-ICD System – the next generation of the Boston Scientific S-ICD System – received CE mark earlier this year, was approved by the Food & Drug Administration (FDA) in March of 2015, launched in Europe starting in May, and became commercially available in the U.S. earlier this month in preparation for a planned full U.S. launch during the third quarter of 2015.

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, our products, product launches, clinical trials and impact of data, 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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[i] Moss AJ, et al. Reduction in inappropriate therapy and mortality through icd programming *N Engl J Med*. 2012;367:2275-2283

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