Boston Scientific Begins Clinical Trial of ACUITY™ X4 LV Pacing Leads and RELIANCE™ 4-FRONT ICD Leads

NATICK, Mass., April 22, 2014 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has conducted the first implant in the clinical trial of the next generation ACUITY™ X4 left-ventricular (LV) pacing leads and RELIANCE™ 4-FRONT defibrillation (ICD) leads. The clinical trial is designed to establish the safety and effectiveness of both lead families and is intended to support U.S. Food and Drug Administration (FDA) approval of these devices.

ACUITY X4 LV leads are quadripolar leads engineered to maximize effectiveness and minimize unnecessary patient interventions after implant. The unique three-dimensional spiral design is intended to minimize floating electrodes resulting in better electrical performance; in addition, dual-fixation zones and the 2.6 French crossing profile are designed to optimize lead stability and reduce the risk of dislodgement. When an ACUITY X4 lead is connected to a Boston Scientific X4 CRT-D, the resulting 17 pacing vector options are designed to improve physicians' ability to manage unexpected complications electronically through programming rather than an invasive lead revision.

The RELIANCE 4-FRONT ICD lead is designed for reliability and performance over the long term. The lead maintains the same design principles as the industry's most reliable ICD lead, the ENDOTAK RELIANCE™ lead, yet offers improved handling and maneuverability. Additionally, the GORE™ coating securely adhered to the defibrillation coils is intended to prevent tissue in-growth and enable both a streamlined implant experience and easier extraction in case of infection.

"For the past 20 years, Boston Scientific has led the industry with regard to lead reliability and performance," said Kenneth Stein, M.D., senior vice president and chief medical officer, Rhythm Management, Boston Scientific. "The ACUITY X4 and RELIANCE 4-FRONT leads are designed to continue this tradition and will provide physicians better options to improve patient care."

The first patient enrollments occurred this week at Wheeling Hospital in Wheeling, W.VA with Dr. Maninder Bedi, and at Central Baptist Hospital in Lexington, KY with Dr. Aaron Hesselson. "The ACUITY X4 portfolio allowed me to choose a lead that matched the patient's anatomy," said Dr. Hesselson.

Likewise, Dr. Bedi noted the advantages of the ACUITY X4 portfolio for his patient. "This patient may have otherwise had to go for an epicardial lead due to the lack of placement options, but the X4 lead got into several branches of a narrow anatomy that other leads may not have been able to access," said Dr. Bedi.

The NAVIGATE X4 trial is a prospective, non-randomized, multi-center, global clinical study designed to support FDA approval. The two principal investigators are Suneet Mittal, MD, director, Electrophysiology, Valley Health System and Martin C. Burke, DO, professor of medicine and director, Heart Rhythm Center, University of Chicago Medical Center. The trial is expected to enroll between 1,542 and 2,290 patients at up to 125 centers in the United States, Canada and Israel. The ACUITY X4 and RELIANCE 4-FRONT leads will be connected to commercially-available Boston Scientific X4 CRT-D devices.

Leads are insulated wires that connect an implantable device to the heart for treatment of sudden cardiac arrest or heart failure. Cardiac Resynchronization Therapy Defibrillation (CRT-D) devices work in conjunction with leads to sense and stimulate (or pace) both right and left ventricles, thus resynchronizing the heart to provide appropriate function. Quadripolar CRT-D systems help physicians address high-pacing capture thresholds and phrenic nerve stimulation, a common complication of CRT therapy due to close proximity of the phrenic nerve to the desired pacing location in the left ventricle.

The ACUITY X4 left ventricular pacing leads and RELIANCE 4-FRONT defibrillator leads are CE Marked. In the United States, they are investigational devices and not available for sale.

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.

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 regulatory approvals, clinical trials, product performance and importance, 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.

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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