Boston Scientific

Boston Scientific Receives U.S. FDA Approval For Quadripolar Leads And Initiates Global Trial To Expand MRI Labeling To The U.S. And Asia

FDA-Approved ACUITY™ X4 Quadripolar Left Ventricular Leads to be used in Trial Pursuing MRI Labeling for Cardiac Defibrillation and Resynchronization Systems

MARLBOROUGH, Mass., Feb. 23, 2016 /PRNewswire/ -- Boston Scientific (NYSE: BSX) has received U.S. Food and Drug Administration (FDA) approval for the ACUITY™ X4 Quadripolar Left Ventricular (LV) leads. The FDA approval of the quadripolar leads, the wires that connect cardiac resynchronization therapy (CRT) devices to the heart, marks the first time the company will offer a full X4 CRT system – both the device and the leads – to the U.S. market.

The family of ACUITY X4 Quadripolar LV leads is engineered with four electrodes along a unique 3D shape. The leads are designed to enable physicians to place them in the vasculature easily and to allow pacing at an optimal site to improve the patient response to CRT therapy.

FDA approval of the ACUITY X4 Quadripolar LV leads was based on data from the NAVIGATE X4 study, a prospective, non-randomized, multicenter clinical trial that enrolled 764 patients. The study successfully met the primary safety and efficacy endpoints through six months of follow up.

"Data collected in the NAVIGATE X4 study demonstrate that these leads are safe and effective for use with CRT devices," said Suneet Mittal, M.D., principal investigator, director of the Electrophysiology Laboratory for Valley Hospital Health System in Ridgewood, N.J. "The approval is a testament to the strength of the data in this trial, which also demonstrated fast lead implant times, stable lead placement, and improved pacing performance resulting from the unique design of the ACUITY X4 leads."

Earlier this month, the company initiated the global ENABLE MRI study, which is intended to support FDA approval for magnetic resonance imaging (MRI) across the company's currently approved implanted cardiac defibrillation (ICD) and CRT systems. The newly approved family of ACUITY X4 Quadripolar LV leads will be used in this study, which is expected to enroll as many as 500 patients at approximately 60 sites worldwide. Trial findings will be submitted to regulatory authorities in Asia and the U.S. when the company requests updated labeling for MRI-conditional use on ICD and CRT systems, including those that have previously been implanted.

"We continue to enhance patient care with the launch of the uniquely designed ACUITY X4 leads, which allow for optimal placement of pacing electrodes to improve the performance of CRT devices," said Kenneth Stein, M.D., Chief Medical Officer, Cardiac Rhythm Management, Boston Scientific. "Additionally, through our pursuit of MRI-conditional labeling, we maintain our commitment to bring new benefits to patients who currently have one of our devices or will receive one in the future."

The MRI-conditional labeling in the U.S. would include current and future families of Extended Longevity (EL) and MINI ICDs and the X4 cardiac resynchronization therapy defibrillator (CRT-D) systems, including leads. In August of 2015, the company received CE Mark on MRI conditional labeling on its EL and MINI ICDs and X4 CRT-D systems, as well as the ACUITY™ X4 quadripolar LV leads, INGEVITY™ and FINELINE™ II pacing leads and RELIANCE® 4-SITE™ and 4-FRONT™ defibrillator leads. The X4 line of CRT-Ds includes the DYNAGEN X4 and INOGEN X4 in the U.S.

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, regulatory approval and clinical trial and its results. 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.

CONTACTS:

Laura Aumann
Media Relations
Boston Scientific Corporation
(651) 582-4251 (office)
Laura.Aumann@bsci.com

Susie Lisa, CFA
Investor Relations
Boston Scientific Corporation
(508) 683-5565 (office)
investor_relations@bsci.com

SOURCE Boston Scientific Corporation

---

https://news.bostonscientific.com/2016-02-23-Boston-Scientific-Receives-U-S-FDA-Approval-For-Quadripolar-Leads-And-Initiates-Global-Trial-To-Expand-MRI-Labeling-To-The-U-S-And-Asia