Boston Scientific

Boston Scientific Announces FDA Clearance of New Heart Failure Lead Delivery System

NATICK, Mass., May 13 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced U.S. Food and Drug Administration clearance of the ACUITY Break-Away™ Lead Delivery System for use with cardiac resynchronization therapy defibrillators (CRT-Ds) and cardiac resynchronization therapy pacemakers (CRT-Ps), both of which treat heart failure.

Leads are insulated wires that carry heart signals to the implanted device and deliver energy from the device to the heart. Leads are inserted into the heart through veins with a lead delivery system. The ACUITY Break-Away Lead Delivery System is designed to place leads in veins of varying sizes, including difficult-to-access veins.

Key features of the ACUITY Break-Away™ Lead Delivery System include:

- An integrated, break-away hemostasis valve designed to minimize blood loss and allow for a streamlined implant experience with fewer steps and instruments used during surgery
- The smallest inner catheter lead delivery on the market enables physicians to deliver a 4 French lead
- Seven outer and two inner guide catheter shapes designed to deliver the lead in a variety of anatomies

"Boston Scientific continues its long tradition of innovation with the introduction of the ACUITY Break-Away Lead Delivery System, which is designed to simplify the implant experience for both patients and physicians," said Kenneth Stein, M.D., Chief Medical Officer, CRM, for Boston Scientific's Cardiology, Rhythm and Vascular Group. "Physicians can use this lead delivery system in combination with our broad range of left ventricular leads, which have a 97 percent implant success rate(1)."

Boston Scientific's left ventricular leads include four designs that provide multiple options for securing the lead to the heart. This lead portfolio also features Electronic Repositioning™, which provides physicians with six configurations for stimulating the left side of the heart even after implant, potentially avoiding an additional surgical procedure.

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: www.bostonscientific.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of 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 product performance, regulatory approvals, our growth strategy, and our market position. 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 IA- *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.

(1) Based on ACUITY® Spiral Lead, EASYTRAK® 3 Lead and ACUITY® Steerable Lead clinical studies.

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