Boston Scientific

Boston Scientific to Immediately Resume Distribution of COGNIS® CRT-Ds and TELIGEN® ICDs in the U.S.

NATICK, Mass., April 15 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that it has received U.S. Food and Drug Administration (FDA) clearance for the two validated manufacturing changes affecting all of its cardiac resynchronization therapy defibrillators (CRT-Ds) and implantable cardioverter defibrillators (ICDs), and that it will immediately resume distribution of its COGNIS® CRT-Ds and TELIGEN® ICDs. The Company is positioned to fully meet customer demand for COGNIS and TELIGEN within 24 hours. COGNIS and TELIGEN represent virtually all of the Company's defibrillator implant volume in the United States.

On March 15th and 16th the Company submitted the two manufacturing changes to the FDA for the following CRT-D and ICD product families: COGNIS, TELIGEN, CONFIENT™, LIVIAN™, PRIZM™, RENEWAL® and VITALITY™. Solely on its own initiative, the Company has conducted an internal review of manufacturing and other changes for these products, as well as the associated regulatory submissions. The review found a few additional instances where the Company did not submit the appropriate documentation for validated manufacturing changes for CONFIENT, LIVIAN, PRIZM, RENEWAL and VITALITY. The Company has now submitted this documentation and is working closely with the FDA to secure clearances to return CONFIENT, LIVIAN, PRIZM, RENEWAL and VITALITY -- the earlier generations of the Company's CRT-D and ICD products -- to market as soon as possible in the United States. These products may continue to be implanted in geographies outside the United States.

The Company's pacemakers and other products were not affected by the ship hold and product removal actions. Geographies outside the United States were never affected – and remain unaffected – by these actions.

"We are pleased that the FDA has cleared the manufacturing changes, and that we are again able to offer COGNIS and TELIGEN to U.S. patients and physicians," said Ray Elliott, President and Chief Executive Officer of Boston Scientific. "We are committed to doing the right thing every time, and we acted voluntarily, swiftly and appropriately to ensure compliance with all regulatory requirements. Our entire sales force is energized and hard at work!"

The Company is evaluating the impact of the ship hold and product removal actions on its financial results and will provide an update with the release of its first quarter earnings. These recent actions may have a material impact on the Company's previously issued guidance, including revenue, operating profit and cash flows for the first quarter and full year of 2010.

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 regulatory approvals, internal systems and processes, product performance and availability, and financial 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.

CONTACT: Paul Donovan
508-650-8541 (office)
508-667-5165 (mobile)
Media Relations
Boston Scientific Corporation

Larry Neumann
508-650-8696 (office)
Investor Relations
Boston Scientific Corporation

SOURCE Boston Scientific Corporation
