Boston Scientific

Boston Scientific Announces FDA Approval of New Heart Failure Lead

NATICK, Mass., May 16 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced U.S. Food and Drug Administration (FDA) approval of its ACUITY® Spiral left ventricular lead for use with cardiac resynchronization therapy defibrillators (CRT-D) and cardiac resynchronization therapy pacemakers (CRT-P), both of which treat heart failure. The ACUITY Spiral lead is the Company's fifth generation left ventricular lead and second in the ACUITY family of left ventricular leads. The product features a spiral fixation design and small lead tip profile (4.1 French tapering to 2.6 French) for placement of the lead in veins of varying sizes, including difficult-to-access veins. A lead is an insulated wire that carries the heart signal to the implanted device and delivers energy from the device to the heart. In most cases, leads are passed into the heart through veins.

"In the U.S. clinical trial, the ACUITY Spiral fixation design provided excellent stability after implant," said John Hummel, M.D., principal investigator of the ACUITY Spiral U.S. clinical trial. "ACUITY Spiral has the smallest left ventricular lead tip profile in the industry, offering greater flexibility to place the lead in veins I may have avoided in the past."

Boston Scientific is also conducting a prospective, multi-center trial designed to collect and analyze real-world performance data for the ACUITY Spiral lead. The study will enroll approximately 1,700 patients in up to 125 centers. Patients will be followed over a period of five years and will be enrolled on Boston Scientific's LATITUDE® Patient Management system, enabling wireless remote management of patients.

"This study demonstrates Boston Scientific's commitment to quality and robust post-market surveillance of new leads," said Arjun Sharma, M.D., Vice President, Patient Safety, Boston Scientific CRM. "The data from this post- market study will provide us with a deeper understanding of the lead's performance in real-world practice and will be a welcome addition to the data we collected from the U.S. clinical trial."

Boston Scientific is the only company to offer four fixation designs that provide stability in a variety of venous anatomies, enabling physicians to select the most appropriate lead for their patients. The ACUITY Spiral lead is designed for use with heart failure devices, such as the COGNIS™ CRT-D, which received FDA approval earlier this week.

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: http://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 approval of our products, new product launches, competitive offerings, 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 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 thereafter. 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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