Boston Scientific

Boston Scientific Begins Clinical Trial of Patients Implanted with INGEVITY™ Pacing Leads

NATICK, Mass., Dec. 17, 2012 /PRNewswire/ -- The first patient has been implanted with the Boston Scientific Corporation (NYSE: BSX) next generation INGEVITY™ pacing leads in a clinical trial designed to establish the safety, performance and effectiveness of the leads. Pacing leads are insulated wires that connect an implantable pacemaker to the heart for treatment of bradycardia, a condition in which the heart beats too slowly, depriving the body of sufficient oxygen. Pacemakers work in conjunction with leads to sense and stimulate (or pace) the heart, thus maintaining an appropriate heart rate for a given level of physical activity.

The INGEVITY pacing lead platform is designed to provide key enhancements in maneuverability, reliability, fixation and electrical performance compared to standard leads available today. In addition, INGEVITY leads are specifically engineered to function in the magnetic resonance imaging (MRI) environment. Many patients with pacemakers are restricted from undergoing MRI scans, as powerful magnets may interfere with pacemaker functionality.

"Our research and development efforts focus on consistency, repeatability and industry-leading reliability," said Kenneth Stein, M.D., senior vice president and chief medical officer of the Cardiac Rhythm Management business at Boston Scientific. "We believe INGEVITY reflects all of these design principles, with the goal of improving the quality of patient care across the globe."

The first patient implant occurred in October in Stockholm, Sweden by Dr. Fredrik Gadler, associate professor, head of Cardiology and director of Pacing and ICD at Karolinska University Hospital.

"I was impressed with the performance of the INGEVITY lead during the implant procedure," said Dr. Gadler. "I felt very in control while maneuvering the lead, which allowed me to place the lead precisely where I intended."

The INGEVITY trial is a prospective, non-randomized, multi-center, global clinical study designed to support U.S. Food and Drug Administration (FDA), CE Mark and other regulatory approvals. The trial is expected to enroll approximately one thousand patients at 100 centers worldwide in 16 countries. The INGEVITY leads are expected to be paired with the Boston Scientific Ingenio™ family of pacemakers.

In the first half of 2013 the company also expects to begin a separate clinical trial, designed to evaluate INGEVITY leads paired with Ingenio pacemakers for use in an MRI setting, to support FDA regulatory approval for this system combination. The company expects to seek approval for this system combination in other markets as well. The Boston Scientific ImageReady™ MR Conditional pacing system, which features Ingenio MR Conditional pacemakers paired with FINELINE™ leads, received CE Mark approval earlier this summer.

INGEVITY pacing leads are investigational devices and not available for sale.

About Boston Scientific

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices that 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 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 launches, product performance 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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