Boston Scientific

Boston Scientific Announces CE Mark Approval and First Implants of Ingevity™ MRI Pacing Leads

First implant took place in France, at the Nouvelles Cliniques Nantaises in Nantes

NATICK, Mass., March 14, 2014 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announces CE Mark approval and European market launch of the INGEVITY™ family of magnetic resonance imaging (MRI) compatible pacing 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. Pacemakers work in conjunction with leads to sense and stimulate (or pace) the heart.

The INGEVITY family offers a comprehensive set of leads that can be placed using a 6 French introducer, including passive and active fixation models. INGEVITY MRI pacing leads are part of the ImageReady™ MR-conditional pacemaker system, which includes VITALIO™ MRI, FORMIO™MRI, ADVANTIO™MRI and INGENIO™MRI pulse generators. When used with the LATITUDE™ NXT patient management system, these devices wirelessly monitor patients for conditions such as atrial arrhythmias.

The first implant of the INGEVITY MRI lead was performed on March 3rd by Daniel Gras, M.D., at the Nouvelles Cliniques Nantaises in Nantes, France. "The INGEVITY MRI lead offers exceptional handling and placement within the heart," said Dr. Gras. "In addition, the Boston Scientific ImageReady™ pacing system could help many patients who may require an MRI scan during their life."

"The INGEVITY MRI pacing leads platform represents a significant milestone in our bradycardia technology and CRM lead portfolio," said Michael Onuscheck, senior vice president and president, Boston Scientific Europe. "We are proud to offer multiple, new and innovative CRM leads engineered for superior long-term clinical performance, including INGEVITY MRI pacing leads, RELIANCE 4-FRONT™ defibrillation leads, and the ACUITY™ X4 CRT family of leads." One of the first implants of the AUTOGEN™ X4 CRT-D system incorporating all three of these new leads was performed by Dr Gianluca Botto, Head of Cardiac Electrophysiology and Pacing at Sant'Anna Hospital in Como, Italy.

The subset of data from the INGEVITY trial supporting CE mark approval demonstrates excellent performance including positive ratings on lead handling and maneuverability from 99.5% of implanters.[1]

The INGEVITY trial series includes prospective, non-randomized, multi-center, global clinical studies to support the INGEVITY family of leads for CE Mark, FDA and other regulatory approvals. Over 1600 patients have been implanted at 78 centers in 16 countries.

INGEVITY MRI, RELIANCE 4-FRONT, ACUITY X4, and AUTOGEN X4 CRT-D are investigational devices and not available for sale in the U.S.

[1] *INGEVITY Active Fixation and Passive Fixation Pace/ Sense Lead Clinical Study. Data on file.*

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 30 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 http://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 new product launches, regulatory approvals, clinical and product performance and importance, 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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