Boston Scientific

# Boston Scientific Begins Clinical Trial To Evaluate New Pacing System in MRI Environment

NATICK, Mass., April 15, 2013 /PRNewswire/ -- The first patient in the United States has been implanted with the Boston Scientific Corporation (NYSE: BSX) next generation ImageReady™ MR Conditional pacing system in the SAMURAI clinical trial. The study is designed to confirm the safety and effectiveness of the system in the magnetic resonance imaging (MRI) environment. Pacing systems are designed to treat bradycardia, a condition in which the heart beats too slowly depriving the body of sufficient oxygen. MRI provides detailed images of organs and tissues without the use of radiation. While those images can help clinicians make informed decisions about treatment and care, most pacemakers are not compatible with MRI technology and therefore patients may not have access to the sophisticated scanning capabilities of the diagnostic system.

The next generation ImageReady pacing system is comprised of the Boston Scientific Ingenio™ MRI pacemaker family and the new INGEVITY™ MRI pacing leads. The proprietary technology is aimed at reducing MRI interference with device performance. In addition, the INGEVITY pacing lead platform is designed to provide key enhancements in handling and fixation compared to standard leads available today, and is specifically engineered to function in the MRI environment.

"Physicians are very limited in device options and therapies labeled for use in the MRI setting," said Ronald Berger, M.D., Ph.D., professor of Medicine, Johns Hopkins Medical Institutions. "The availability of a pacing system specifically designed to allow patients with pacemakers to undergo a broad set of MRI scanning conditions will advance the quality of patient care. The Ingenio MRI pacemaker family also offers pacing technologies not previously available in devices designed for the MRI environment."

The ImageReady pacing system offers technologies exclusive to Boston Scientific, including RightRate™ rate adaptive pacing with the Minute Ventilation sensor, the only sensor clinically proven to restore chronotropic competence[1]; RYTHMIQ™, which is designed to minimize unnecessary RV pacing without clinically significant pauses; and LATITUDE™ NXT, which is geared towards minimizing clinic and patient burden with wireless remote follow-up.

"The ImageReady system is another example of our continued commitment to meaningful innovation," said Kenneth Stein, M.D., chief medical officer, Cardiac Rhythm Management, Boston Scientific. "Our mission is to improve outcomes by providing patients and their physicians with access to the most advanced device therapies and diagnostic technologies."

The SAMURAI trial is a prospective, open-label, two-group randomized, multi-center, global clinical study designed to support U.S. Food and Drug Administration regulatory approval. The trial is expected to enroll approximately 363 patients at 45 centers in seven countries. The first patient implant in the United States occurred at OhioHealth's Riverside Methodist Hospital in Columbus, Ohio by Sreedhar Billakanty, M.D. Dr. Billakanty is the co-investigator of the SAMURAI study at OhioHealth along with Gregory Kidwell, M.D., system medical director of Electrophysiology Services. The first study implant in the world occurred in Malaysia at the Institut Jantung Negara (Kuala Lumpur) by Razali Omar, M.D.

The ImageReady pacing system is under clinical investigation and not currently available for sale in the United States.

**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 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 and launch cadence, regulatory approvals, clinical trials, 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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[1] Chronotropic competence is defined by the Model of the Cardiac Chronotropic Response to Exercise. Wilkoff B, Corey J, Blackburn G. A mathematical model of the cardiac chronotropic response to exercise. *Journal of Electrophysiology*. 1989;3:176–180. Refer to the Physician's System Guide for more information on adaptive-rate therapy. Additional clinical performance was assessed using INSIGNIA® Ultra clinical data with the AutoLifestyle® feature programmed On. Boston Scientific. Data on file. www.bostonscientific.com/ifu

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