Boston Scientific

Boston Scientific Receives U.S. FDA Approval For ImageReady™ MR-Conditional Pacing System

FDA approval includes ACCOLADE™ MRI and ESSENTIO™ MRI pacemakers and INGEVITY™ MRI pacing leads

MARLBOROUGH, Mass., April 25, 2016 /PRNewswire/ -- Boston Scientific (NYSE: BSX) has received U.S. Food and Drug Administration (FDA) approval for a suite of products deemed safe for use in a magnetic resonance imaging (MRI) environment. The ImageReady™ MR-Conditional Pacing System, which includes ACCOLADE™ MRI and ESSENTIO™ MRI pacemakers, as well as the new INGEVITY™ MRI pacing leads, is designed to treat bradycardia, a condition in which the heart beats too slowly. Patients implanted with the full system are able to receive full-body MR scans in 1.5 Tesla environments when conditions of use are met.

The newly-approved family of INGEVITY MRI pacing leads includes active and passive fixation models. This marks the first time a passive fixation pacing lead is approved for U.S. patients undergoing MR scans.

Approval of the INGEVITY MRI leads, as well as the full ImageReady System, was based on data from two global clinical trials. The INGEVITY trial, a prospective, non-randomized study, enrolled 1,036 patients and assessed safety, performance and effectiveness of the leads in patients with a single or dual chamber pacemaker. The SAMURAI trial, a prospective, randomized study, enrolled 351 patients and evaluated safety and effectiveness of the ImageReady System for use in patients with a single or dual chamber pacemaker when used in an MRI environment.

"As shown in the SAMURAI trial, the ImageReady System gives physicians reassurance that they are implanting pacemakers that are safe in an MRI environment should their patients need scans in the future," said Ronald D. Berger, M.D., Ph.D., principal investigator of the SAMURAI trial and professor of medicine and biomedical engineering at Johns Hopkins Medical Institutions. "The study demonstrated the INGEVITY MRI leads had no MR-related complications and very low rates of complications overall."

The ImageReady System offers automatic daily monitoring via the LATITUDE™ NXT Patient Management System. An increasingly important tool for physicians, automatic daily monitoring has been shown to improve survival in patients with pacemakers[1]. The LATITUDE NXT wireless system allows for earlier intervention and improved patient outcomes by providing physicians with device and patient information through customizable alerts.

"With a pacing system specifically designed with automatic remote monitoring that also allows patients to undergo MR scans, we are further advancing the quality of patient care," said Kenneth Stein, M.D., chief medical officer, Rhythm Management, Boston Scientific. "We believe that the daily monitoring capability of the ImageReady System, coupled with advanced diagnostics, will help physicians identify concerns and ultimately initiate patient care sooner."

The company is also actively pursuing MRI compatibility for their currently approved implanted cardiac defibrillation (ICD) and cardiac resynchronization therapy (CRT) systems via the global ENABLE MRI study, which was initiated earlier this year. Trial findings will be submitted to regulatory agencies in Asia and the U.S., when the company requests updated labeling for MR-conditional use on ICD and CRT systems, including those that have been previously implanted.

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 35 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 our business plans, regulatory approvals and product performance and impact. 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.

CONTACTS:
Laura Aumann
Media Relations
Boston Scientific Corporation
(651) 582-4251 (office)
Laura.Aumann@bsci.com

Susie Lisa, CFA
Investor Relations
Boston Scientific Corporation
(508) 683-5565 (office)
investor_relations@bsci.com

[1] Varma N, Piccini JP, Snell J, Fischer A, Dalal N, Mittal S. "The Relationship Between Level of Adherence to Automatic Wireless Remote Monitoring and Survival in Pacemaker and Defibrillator Patients." *J Am Coll Cardiol.* 2015 Jun 23; 65(24):2601-10.

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