Boston Scientific

Boston Scientific Announces U.S. FDA Approval Of EMBLEM™ MRI S-ICD System

Approval Grants MR-Conditional Labeling to All EMBLEM S-ICD Systems, Expands ImageReady™ Portfolio

MARLBOROUGH, Mass., Aug. 9, 2016 /PRNewswire/ -- Boston Scientific (NYSE: BSX) has received U.S. Food and Drug Administration (FDA) approval for the EMBLEM™ MRI Subcutaneous Implantable Defibrillator (S-ICD) System, as well as magnetic resonance (MR) conditional labeling for all previously implanted EMBLEM S-ICD Systems. The new EMBLEM MRI S-ICD System is the latest addition to the company's growing line of ImageReady™ MR-conditional devices, which allow patients to undergo magnetic resonance imaging (MRI) safely.

The EMBLEM S-ICD System is a proven treatment option for patients at risk of sudden cardiac arrest, that leaves the heart and vasculature untouched, thus reducing the risk of complications associated with conventional transvenous implantable cardioverter-defibrillator leads.

"Now with FDA approval, patients receiving the EMBLEM MRI S-ICD System, as well as patients who previously were implanted with an EMBLEM S-ICD System, have reassurance they can safely undergo MR scans while remaining protected from cardiac arrest," said Kenneth Stein, M.D., chief medical officer, Rhythm Management, Boston Scientific.

Boston Scientific received CE Mark for the EMBLEM MRI S-ICD System earlier this year and began commercialization in Europe in June. In addition to MR-conditional labeling, the device introduces two new features to the market – SMART Pass technology and Atrial Fibrillation (AF) Monitor™. The SMART Pass technology, also being added to previously implanted EMBLEM S-ICD Systems through a software update, increases the accuracy of the INSIGHT™ Algorithm to help ensure patients receive appropriate therapy from the device only when necessary. The AF Monitor feature is a detection tool designed to alert physicians after the identification of AF so they can make more informed treatment decisions for their patients.

Earlier this year, the company received FDA approval for the ImageReady MR-Conditional Pacing System, which includes ACCOLADE™ MRI and ESSENTIO™ MRI pacemakers as well as INGEVITY™ MRI pacing leads, designed to treat bradycardia. Patients implanted with the full system are able to receive full-body MR scans in a 1.5 Tesla environment when conditions of use are met. Additionally, the company is actively pursuing MRI compatibility for their currently approved implanted cardiac defibrillation and cardiac resynchronization therapy systems via the global ENABLE MRI study.

For more information on the EMBLEM S-ICD Systems visit www.bostonscientific.com/sicd.

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:

U.S. Media: Laura Aumann
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

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