Boston Scientific announces CE mark for MRI labeling of EMBLEM™ S-ICD Systems

European Approval Granted for Third-Generation System and All Previously Implanted, Second-Generation Systems

Boston Scientific (NYSE: BSX) has received CE Mark approval for the new 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 EMBLEM S-ICD Systems are treatment options for patients at risk of sudden cardiac arrest (SCA) that leave the heart and vasculature untouched, reducing the risk of complications associated with transvenous implantable cardioverter-defibrillators (TV-ICDs). Initial market release of the new EMBLEM MRI S-ICD System has begun in a small number of European centers with a broad European launch scheduled for early this summer.

In Europe, the EMBLEM MRI S-ICD System joins the growing family of ImageReady™ MR-conditional devices, all of which are labeled safe for use in a magnetic resonance image setting when conditions of use are met. Patients receiving the EMBLEM MRI S-ICD System as well as patients who previously were implanted with an EMBLEM S-ICD System are now able to undergo full-body MR scans safely in 1.5 Tesla environments when conditions of use are met.

“These approvals give reassurance to physicians and their patients that they have access to any future MR scan needs, and underscores the Boston Scientific commitment to gain MR-conditional labeling on high-voltage devices that are being implanted today,” said Kenneth Stein, M.D., chief medical officer, Rhythm Management, Boston Scientific. “Further, the EMBLEM S-ICD System is a compelling treatment option for the majority of ICD-indicated patients that provides protection from cardiac arrest without invading the heart and blood vessels.”

The EMBLEM MRI S-ICD System also includes two new features, SMART Pass technology and Atrial Fibrillation (AF) Monitor™. The SMART Pass technology will help ensure patients receive therapy from the device only when necessary by enhancing the INSIGHT™ Algorithm, which identifies and classifies a heart rhythm for effective arrhythmia treatment. This novel feature will also be added to previously implanted EMBLEM S-ICD Systems through a software update. The AF Monitor feature of the EMBLEM MRI S-ICD System is a new detection tool designed to alert physicians after the identification of AF so they can make more informed treatment decisions for their patients.

The company is actively pursuing U.S. Food and Drug Administration (FDA) approval of the EMBLEM MRI S-ICD System as well as MR-conditional labeling for previously implanted EMBLEM S-ICD Systems. Additionally, the global ENABLE MRI study, initiated earlier this year, is intended to support FDA approval for MR-conditional labeling across the company’s currently approved ICD and cardiac resynchronization therapy systems.

For more information on the EMBLEM S-ICD Systems visitwww.sicdsystem.com.

In the U.S., the EMBLEM MRI S-ICD System is not available for sale.

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.eu 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.

1Survival probability is comprised of all RELIANCE and RELIANCE G models combined as one population. Data source and data cut off is based on the BSC Q2 2012 Product Performance report. Data and calculations on file.

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