Boston Scientific

Boston Scientific Announces U.S. FDA Approval for MRI Labeling on High-Voltage Devices and U.S. Launch of Resonate™ Devices with the HeartLogic™ Heart Failure Diagnostic

MARLBOROUGH, Mass., Sept. 25, 2017 /PRNewswire/ -- Boston Scientific (NYSE: BSX) has launched the Resonate™ family of implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy defibrillator (CRT-D) systems featuring the HeartLogic™ Heart Failure Diagnostic to help physicians improve heart failure (HF) management. The new devices, which are approved by the U.S. Food and Drug Administration for conditional use in a magnetic resonance imaging (MRI) environment, also combine the company's SmartCRT™ Technology with industry-leading EnduraLife™ Battery Technology to improve patient management through personalized care.

Experience the interactive Multichannel News Release here: https://www.multivu.com/players/English/7839552-boston-scientific-resonate-devices/

The newly introduced HeartLogic Diagnostic alerts physicians of worsening HF by combining data from sensors evaluating heart sounds, respiration rate and volume, thoracic impedance, heart rate and activity. The alert is the first and only heart failure diagnostic in an implantable device that has been validated to have an observed sensitivity of 70% as well as the ability to provide weeks of advance notice – a median of 34 days ahead of an impending HF event – and low burden for detecting indications of worsening HF.[1]

"The HeartLogic Diagnostic provides physicians the ability to pivot from reactive heart failure treatment to proactive care with a goal of improving patient outcomes and reducing heart failure-related hospitalizations," said Kenneth Stein, M.D., senior vice president and chief medical officer, Rhythm Management and Global Health Policy, Boston Scientific. "We believe the new features included in this family of devices offer physicians an unprecedented level of confidence when caring for patients with heart failure."

In addition to the HeartLogic Diagnostic, all CRT-Ds in the Resonate family of devices are enabled with SmartCRT Technology to help physicians customize where, when, and how to pace the lower chambers of the heart using the Multisite Pacing capability for multi-electrode pacing. The SmartCRT Technology, coupled with EnduraLife Battery Technology, provides physicians with an unparalleled ability to tailor device settings according to individual patient needs, without fear of adversely draining the battery and causing unnecessary replacement procedures.

The company recently began enrolling patients in the MANAGE-HF study to evaluate further the HeartLogic Diagnostic and has initiated a series of clinical trials to demonstrate improved response to CRT therapy with the SmartCRT Technology.

"Through the MANAGE-HF study we will be able to realize fully the capabilities of the HeartLogic Diagnostic in clinical practice," said Dr. Adrian Hernandez, principal investigator of the MANAGE-HF study, director of health services and outcomes research at the Duke Clinical Research Institute and vice dean of clinical research at Duke University School of Medicine. "We look forward to collecting additional data on how the alert can enable improved patient outcomes."

The MR-conditional labeling allows patients implanted with specific models of the company's Resonate family of devices to receive full-body MR scans in 1.5 Tesla environments when conditions of use are met. This capability extends beyond the Resonate family and includes those patients who were previously implanted with AUTOGEN™, DYNAGEN™, INOGEN™ ICD and CRT-D devices. MRI approval was based on clinical trial results from the global ENABLE MRI study, which was completed earlier this year.

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, clinical trials, 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
(651) 582-4251 (office)
Laura.Aumann@bsci.com

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

[1] Boehmer, J et al., JACC-HF, 2017;5(3),2 1 6 – 2 56.

SOURCE Boston Scientific Corporation

Additional assets available online: Video (2) Photos (4)

https://news.bostonscientific.com/2017-09-25-Boston-Scientific-Announces-U-S-FDA-Approval-for-MRI-Labeling-on-High-Voltage-Devices-and-U-S-Launch-of-Resonate-TM-Devices-with-the-HeartLogic-TM-Heart-Failure-Diagnostic