Boston Scientific

Boston Scientific Receives U.S. FDA Approval For Resonate™ Family Of High-Voltage Devices

New Devices Combine Longest-Lasting Battery Technology, Therapy Optimization and HeartLogic™ Heart Failure Diagnostics

MARLBOROUGH, Mass., May 9, 2017 /PRNewswire/ -- Boston Scientific (NYSE: BSX) has received U.S. Food and Drug Administration (FDA) approval for the Resonate™ family of implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy defibrillator (CRT-D) systems. The approval includes new features in the Resonate devices including SmartCRT™ technology with Multisite Pacing capability for multi-electrode pacing, and compatibility with the HeartLogic™ Heart Failure Diagnostic Service to help physicians improve heart failure (HF) management.

All Resonate devices are powered by the company'sEnduraLife™ Battery Technology, which has nearly two times the usable battery capacity as certain competitive devices,[1,2] an essential factor when considering the lifelong needs of patients receiving ICD or CRT therapy. Recent guidance issued by the National Institute for Health and Care Excellence (NICE) in March 2017 recommended the use of EnduraLife-powered CRT-Ds to reduce the number of avoidable replacement procedures a patient may have to undergo, thereby offering improved outcomes for patients and potential savings to the National Health Service (NHS) in England of approximately £6 million in the first five years.

The company has initiated a series of clinical trials, the SMART Registry, SMART CRT Study and SMART MSP, to demonstrate improved response to CRT therapy with SmartCRT technology, which helps physicians optimize where, when, and how to pace the lower chambers of the heart.

"These trials will add to the body of evidence showing CRT therapy can be tailored to individual patient characteristics at the time of implant, while adjusting device programming solutions over the life of the device without fear of adversely draining the device battery and causing unnecessary replacement procedures," said Dr. Michael Gold, principal investigator of the SMART CRT study and the Michael E. Assey professor of medicine at The Medical University of South Carolina, Charleston.

"We are changing the treatment landscape by combining industry-leading device longevity with innovative solutions that will provide clinicians with tools to manage heart failure more effectively," said Kenneth Stein, M.D., senior vice president and chief medical officer, Rhythm Management and Global Health Policy, Boston Scientific. "Our post-approval studies for the HeartLogic service, including MANAGE-HF, will gather additional evidence to illustrate how these alerts, which detect impending heart failure decompensation, can improve patient outcomes."

This FDA approval follows on the February 2017 CE Mark and subsequent commercialization for the Resonate family of ICD and CRT-D devices.

[1] Medtronic Evera XT VR DVBB2D4 Device Manual page 25.

[2] Boston Scientific Implantable Cardioverter Defibrillator Physician's Technical Manual 359050-003 EN US 2014-01 page 30.

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.

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