Boston Scientific

FDA Advisory Panel Unanimously Recommends Expanded Indication for Boston Scientific's Heart Failure Devices Based on Landmark MADIT-CRT Trial

Company's CRT-Ds recommended for asymptomatic and mild heart failure patients

NATICK, Mass., March 18 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that the Circulatory System Devices Panel of the U.S. Food and Drug Administration (FDA) has unanimously recommended approval of an expanded indication for its cardiac resynchronization therapy defibrillators (CRT-Ds), including the COGNIS® CRT-D. The panel recommended the expansion include the majority of the studied population of the landmark MADIT-CRT clinical trial, which evaluated the ability of these devices to slow the progression of heart failure in patients with asymptomatic or mild heart failure.

"Boston Scientific welcomes the panel's decision to recommend expanding the current indication to include the majority of the MADIT-CRT population," said Hank Kucheman, Executive Vice President and Group President, Cardiology, Rhythm and Vascular for Boston Scientific. "If an expanded indication is approved by the FDA, many additional heart failure patients would be eligible for this therapy, which has been clinically proved to slow the progression of this severe and life-limiting condition."

If approved, Boston Scientific would become the only company with an FDA-approved CRT-D for high-risk New York Heart Association (NYHA) Class I and II(1) patients with Left Bundle Branch Block (LBBB) morphology and sinus rhythm. These patients accounted for 70 percent of the MADIT-CRT population. Currently, heart failure patients must be defined as NYHA Class III or IV to be indicated for a CRT-D device.

In response to a request from the FDA, Boston Scientific worked with the MADIT-CRT Executive Committee to perform an extensive subgroup analysis of the trial data. The subgroup analysis showed that a simple finding on an electrocardiogram of LBBB was the best baseline characteristic in the trial to predict which asymptomatic or mild heart failure patients were most likely to benefit from a CRT-D.

LBBB is a condition in which the activation of the left ventricle is delayed. As a result, portions of the left ventricle contract later than the rest of the left ventricle and right ventricle, reducing the heart's pumping ability. The intent of cardiac resynchronization therapy is to restore synchronous contraction of the ventricles. Sinus rhythm refers to the normal electrical activation of the upper chambers of the heart.

Results of the MADIT-CRT trial were published in the October 2009 issue of the *New England Journal of Medicine.* The primary endpoint showed that Boston Scientific's CRT-Ds were associated with a 34 percent relative reduction in the risk of all-cause mortality or first heart failure event in asymptomatic and mild heart failure patients, when compared to standard implantable cardioverter defibrillators (ICDs) ($p < 0.001$). In addition, data presented to the panel demonstrated that CRT-Ds reduced the relative risk of heart failure events by 42 percent when compared to ICD therapy. MADIT-CRT is the world's largest randomized study of NYHA Class I and II patients, with more than 1,800 patients enrolled at 110 centers worldwide.

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: www.bostonscientific.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of 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 product performance, clinical outcomes, regulatory approval of our products, and our growth strategy. 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 thereafter. 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.

(1) MADIT-CRT patients are asymptomatic or mildly symptomatic, NYHA Class I (ischemic) and Class II (ischemic and non-ischemic). High-risk is defined as QRS width >/= 130 milliseconds and Left Ventricular Ejection Fraction

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