Boston Scientific Receives Exclusive Expanded Indication for Its CRT-Ds

Boston Scientific

NATICK, Mass., Sept. 16 /PRNewswire-FirstCall [1]/ -- Boston Scientific Corporation (NYSE: BSX) today announced that the U.S. Food and Drug Administration (FDA) has approved an expanded indication for its cardiac resynchronization therapy defibrillators (CRT-Ds), including the COGNIS® CRT-D. The exclusive expanded indication is effective immediately and makes Boston Scientific CRT-Ds the only devices approved by the FDA for patients in all New York Heart Association (NYHA) classes of heart failure(1).

The Company's CRT-Ds had previously been approved for NYHA Class III and IV patients. The expanded indication approves Boston Scientific CRT-Ds for use in high risk(2) NYHA Class I and II patients with Left Bundle Branch Block(3) (LBBB). These patients accounted for 70 percent of the MADIT-CRT clinical trial population.

"The MADIT-CRT trial demonstrated that Boston Scientific's CRT-Ds reduce death and heart failure events, even for patients without symptoms," said Kenneth Stein, M.D., Senior Vice President and Chief Medical Officer, CRM, for Boston Scientific's Cardiology, Rhythm and Vascular Group. "Preventing or delaying a first heart failure event in NYHA Class I and II patients with LBBB is critical because these patients are eight times more likely to have a recurring event after their initial event."

In response to a request from the FDA, Boston Scientific worked with the MADIT-CRT Executive Committee to perform further analysis of the trial data to determine if there were additional criteria to identify patients at risk for heart failure. The Company's analysis showed that LBBB was the best baseline characteristic to differentiate which Class I and II patients would be most likely to benefit from a CRT-D. MADIT-CRT data demonstrated that patients with LBBB who received CRT-D therapy showed a relative risk reduction of all-cause mortality or first heart failure event of 57 percent when compared to those who received implantable cardioverter defibrillator therapy ($p<0.001$).

"We are extremely pleased with the FDA's decision to expand the indication for Boston Scientific CRT-Ds, which substantially broadens the population of heart failure patients who can benefit from this therapy," said Hank Kucheman, Executive Vice President and Group President, Cardiology, Rhythm and Vascular for Boston Scientific. "The addition of LBBB to the indication provides a strong, objective identifier of patients eligible for a CRT-D, meeting the needs of both implanting and referring physicians."

MADIT-CRT is the world's largest randomized CRT-D study of NYHA Class I and II

patients, with more than 1,800 patients enrolled at 110 centers worldwide.

For a copy of the technical reference guide, which includes important information for use in the indicated patient population, call 1.800.CARDIAC (227.3422) or 1.866.484.3268.

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 [2].

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 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) The NYHA clinical classifications of heart failure rank patients as Class I-II-III-IV, according to the degree of symptoms or functional limits, from asymptomatic to bed

ridden.

(2) High-risk is defined as QRS width greater than or equal to 130 milliseconds and Left Ventricular Ejection Fraction less than or equal to 30 percent. MADIT-CRT patients are asymptomatic or mildly symptomatic, NYHA Class I (ischemic) and Class II (ischemic and non-ischemic).

(3) 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.

SOURCE [3]

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