Boston Scientific

Video: MADIT-CRT Trial Results Provide Clinical Evidence That Cardiac Resynchronization Therapy Significantly Slows Heart Failure Progression

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NATICK, Mass., and BARCELONA, Spain
(NYSE:BSX)

NATICK, Mass., and BARCELONA, Spain, Sept. 1 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced final results from the landmark MADIT-CRT trial, which were published by the *New England Journal of Medicine* and presented during a Hot Line session at the annual European Society of Cardiology (ESC) Congress in Barcelona.

To view the Multimedia News Release, go to: http://www.prnewswire.com/mnr/bostonscientific/36500/

Arthur Moss, M.D., Professor of Medicine at the University of Rochester Medical Center and Principal Investigator of the trial, presented the MADIT-CRT data. The primary endpoint showed that Boston Scientific's cardiac resynchronization therapy defibrillators (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 (NYHA Class I and II(1)) heart failure patients, when compared to standard implantable cardioverter defibrillators (ICDs) (p=0.001).

In addition, MADIT-CRT data showed that:

- CRT-D therapy reduces the relative risk of heart failure events by 41 percent when compared to ICD therapy (p< 0.001).
- Patients treated with CRT-D therapy showed an improvement of 11 percent in Left Ventricular Ejection Fraction(2) after one year, compared to a three percent improvement for ICD patients.

"The MADIT-CRT Executive Committee anticipated that the benefit for the CRT-D therapy group would be dominated by a reduction in heart failure events and the data overwhelmingly confirm that," said Dr. Moss. "Furthermore, CRT-D therapy showed an equal benefit in both ischemic and non-ischemic(3) patients. The MADIT-CRT data are compelling and help bridge a clinical gap in our understanding of heart failure in Class I and II patients."

"The publication of the manuscript by the *New England Journal of Medicine* and the presentation of MADIT-CRT data at ESC highlight the importance of this study, which clearly demonstrates that CRT-D therapy slows the progression of heart failure, further delaying the onset of more severe and life-limiting conditions," said Fred Colen, President, Boston Scientific Cardiac Rhythm Management. "We look forward to working with the FDA as we seek approval for an expanded indication for our CRT-D devices, based on these strong results."

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 in 14 countries. Currently, heart failure patients must be defined as NYHA Class III or IV to be indicated for CRT-D therapy. However, approximately 70 percent of all heart failure patients in the U.S. fall into Class I or II. Nearly 22 million people worldwide, including more than 5.5 million Americans, suffer from some form of heart failure.

MADIT-CRT is an important continuation of Boston Scientific's exclusive sponsorship of landmark clinical trials that have broken new ground and helped improve outcomes for high-risk cardiac patients worldwide. More than 80 percent of U.S. patients who receive an ICD or CRT-D were first indicated for this life-saving therapy through clinical research(4) sponsored by Boston Scientific.

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 high risk (asymptomatic or mildly symptomatic, New York Heart Association Class I and II). 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%. The New York Heart Association clinical classifications of heart failure patients rank patients as Class I-II-III-IV, according to the degree of symptoms or functional limits, from asymptomatic to bed ridden.

(2) Left Ventricular Ejection Fraction (LVEF) is a measurement of how well the heart is pumping. People with healthy hearts usually have an LVEF of greater than or equal to 50%. Patients who were candidates for the MADIT-CRT study had an LVEF of less than or equal to 30%.

(3) Ischemic patients suffer from Coronary Artery Disease (CAD).

(4) Trials include MADIT, MADIT-II, CONTAK-CD, and COMPANION.

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