

## **MADIT-CRT Trial Data Show Women Received Greater Benefit From CRT-Ds Than Men**

NATICK, Mass. and NICE, France, June 18 [/PRNewswire-FirstCall/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced results from a sub-analysis of the MADIT-CRT trial data that showed women received a greater clinical benefit from its cardiac resynchronization therapy defibrillators (CRT-Ds) than men. The results were presented during the 17<sup>th</sup> Cardiostim World Congress by Jonathan Steinberg, M.D., Chief of Cardiology and Director of the Al-Sabah Arrhythmia Institute, St. Luke's-Roosevelt Hospital Center, New York.

The sub-analysis demonstrated that both men and women experienced significant benefit from cardiac resynchronization therapy. However, women experienced a 70 percent reduction in heart failure events compared to a 35 percent reduction for men. Additional analysis demonstrated that women with asymptomatic or mild heart failure experienced a 72 percent reduction in all-cause mortality.

"There are a number of factors that may explain why women experienced a greater benefit than men," said Arthur Moss, M.D., Professor of Medicine at the University of Rochester Medical Center and Principal Investigator of the MADIT-CRT trial. "CRT-D therapy is designed to improve the heart's overall pumping ability and women are more likely than men to have non-ischemic heart disease, which typically affects the entire heart rather than a single region and can lead to reduced pumping strength, abnormal heart rhythms and disturbances in the heart's electrical system. Men are more likely to have ischemic heart disease, also known as coronary artery disease, which often leads to a more localized impact on the heart."

"These findings are noteworthy because CRT-D therapy has historically been underutilized in women compared to men with the same level of heart disease," said Kenneth Stein, M.D., Chief Medical Officer, CRM, for Boston Scientific's Cardiology, Rhythm and Vascular Group. "Boston Scientific believes that all patients should have equal access to high-quality cardiovascular care regardless of gender. We believe these findings will help reduce treatment disparities between men and women."

MADIT-CRT is the world's largest randomized CRT-D study of New York Heart Association (NYHA) Class I and II patients(1), with more than 1,800 patients enrolled at 110 centers worldwide. Results of the MADIT-CRT trial were published in the October 2009 issue of the *New England Journal of Medicine*. Boston Scientific currently has an application under review with the U.S. Food and Drug Administration for the expansion of its CRT-D indication to include high-risk(2) NYHA Class I and II patients with Left Bundle Branch Block.

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](http://www.bostonscientific.com).

(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. MADIT-CRT patients are asymptomatic or mildly symptomatic, NYHA Class I (ischemic) and Class II (ischemic and non-ischemic).

(2) High-risk is defined as QRS width  $\geq$  130 milliseconds with Left Ventricular Ejection Fraction

### **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.

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