Boston Scientific

# MADIT-CRT Trial Meets Primary Endpoint

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**Landmark trial shows Boston Scientific CRT-Ds slow the progression of heart failure in asymptomatic and mildly symptomatic patients**

NATICK, Mass., June 23 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) and the University of Rochester Medical Center today announced that the landmark MADIT-CRT trial has met its primary endpoint. Preliminary results show Boston Scientific cardiac resynchronization therapy defibrillators (CRT-Ds) to be associated with a significant 29 percent reduction (p=0.003) in death or heart failure interventions when compared to traditional implantable cardioverter defibrillators (ICDs). High risk(1), asymptomatic or mildly symptomatic, New York Heart Association (NYHA) Class I and II(2) patients were enrolled in MADIT-CRT. The MADIT-CRT Executive Committee expects to present and publish the trial's full results later this year.

MADIT-CRT, sponsored exclusively by Boston Scientific, demonstrates that early intervention with cardiac resynchronization therapy can slow the progression of heart failure. It is the world's largest randomized NYHA Class I/II CRT-D trial, with more than 1,800 patients enrolled at 110 centers in 14 countries. The trial is being conducted under the leadership of Principal Investigator Arthur J. Moss, M.D., Professor of Medicine at the University of Rochester Medical Center.

"We are very encouraged by these initial positive results, and we are hopeful they will eventually lead to a wider population of heart failure patients being treated with CRT-D therapy," said Fred Colen, President, Boston Scientific CRM. "I would like to congratulate Dr. Moss, the Executive Committee and all the MADIT-CRT investigators on a well designed and well executed clinical trial. Boston Scientific is proud to continue the tradition of supporting advances in indications in the CRM space through trials like MADIT-CRT. More than 80 percent of U.S. patients who receive an ICD or CRT-D were first indicated for this therapy by a clinical trial sponsored by Boston Scientific or its predecessors(3)."

MADIT-CRT is providing insight into the potential of CRT-D therapy to intervene earlier in the natural progression of heart failure. Currently, patients must be in NYHA Class III/IV heart failure 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 approximately 5.5 million Americans, suffer from some form of heart failure.

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) 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.

(2) The New York Heart Association 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.

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

CONTACT: Paul Donovan
508-650-8541 (office)
508-667-5165 (mobile)
Media Relations
Boston Scientific Corporation

Larry Neumann
508-650-8696 (office)
Investor Relations
Boston Scientific Corporation

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