Boston Scientific Offers New CRT-D Warranty Program Covering Phrenic Nerve Stimulation

Boston Scientific

NATICK, Mass., May 5, 2011 /PRNewswire [1]/ -- Boston Scientific Corporation (NYSE: BSX) today announced that it is offering a new warranty program in the U.S. that covers its cardiac resynchronization therapy defibrillator (CRT-D) devices and leads in the event of chronic phrenic nerve stimulation (PNS).

"Under the program, implanting centers in the U.S. can qualify for a full refund if they have to replace a Boston Scientific COGNIS® CRT-D device, attached to any Boston Scientific bipolar left ventricular (LV) lead, with a competitive device due to unmanageable PNS within six months post-implant," said Hank Kucheman, Executive Vice President and Group President, Cardiology, Rhythm and Vascular for Boston Scientific. "With this warranty program, we are firmly standing behind the performance of our CRT-D devices and LV lead portfolio to ensure patients get the heart failure therapy they need without complications related to phrenic nerve stimulation."

PNS is an occasional complication of CRT therapy due to close proximity of the phrenic nerve to the desired pacing location in the left ventricle. It causes the diaphragm to contract, resulting in a "hiccup-like" sensation and patient discomfort. To avoid PNS when it occurs, physicians attempt to reprogram the device to use a different pacing configuration. If this fails to correct the issue, physicians must manually reposition the lead (insulated wire used to stimulate the heart) into a new location. If PNS manifests after the implant procedure has been completed, lead repositioning would require a second surgery.

"This warranty is based on confidence in our CRT-D system's performance and physicians' ability to avoid PNS when using it," said Kenneth Stein, M.D., Chief Medical Officer, Cardiac Rhythm Management for Boston Scientific. "Physicians must also consider the entire system when choosing which device to implant. Boston Scientific has the smallest and thinnest high-energy devices on the market with excellent longevity and proven long-term lead reliability. Our clinical evidence also shows our LATITUDE® remote monitoring system helps physicians manage their heart failure patients."

ELECTION trial data, recently published in *Europace*, demonstrated that Boston Scientific bipolar LV leads and devices, with Electronic Repositioning™ and three proprietary pacing configurations, successfully avoided PNS. In particular, the study reported:

- Boston Scientific's bipolar CRT system successfully avoided PNS without lead repositioning more than 95 percent of the time during the acute implant

procedure. In addition, in the ELECTION trial, not a single patient required reoperation to reposition a lead due to chronic PNS. St. Jude's published data indicated an ability to avoid PNS with its quadripolar lead between 89 percent and 95 percent of the time(1)(2).
- Real-world performance data showed that current Boston Scientific bipolar LV leads have an acute dislodgement rate of less than 1 percent within 30 days post-implant (0.90 percent based on latest Product Performance Report). St. Jude's quadripolar lead had a dislodgement rate of 3.7 percent in a published study(2).

Additional study data evaluating St. Jude's bipolar and quadripolar LV leads, include:

- Available quadripolar data showed that physicians programmed the two distal electrodes as the cathode instead of the proximal electrodes, essentially programming it as a bipolar lead 96 percent of the time(3).
- St. Jude's published data indicated no significant differences in implant time, fluoroscopy time or LV lead implant time between its quadripolar and bipolar LV lead cases(1).

About 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 [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 new product launches and launch cadence, warranty programs, regulatory approvals, clinical trials and studies, product performance and competitive offerings. 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; product performance; 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 hereafter. 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. Forleo GB, Della Rocca DG et al, Left ventricular pacing with a new quadripolar transvenous lead for CRT: Early results of a prospective comparison with conventional implant outcomes. Heart Rhythm. 2011

2. Shetty AK, Duckett SG et al, Initial Single-Center Experience of a Quadripolar Pacing Lead for Cardiac Resynchronization Therapy. PACE. 2010

3. Sperzel JK, Danshcel W et al, Initial Clinical Experience with a Novel Left Ventricular Quadripolar Lead, HRS 2010 – poster presentation

SOURCE [3]

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