Boston Scientific

Boston Scientific Announces FDA Approval for New Devices to Treat Heart Failure and Sudden Cardiac Death

NATICK, Mass., May 13 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced U.S. Food and Drug Administration (FDA) approval of its COGNIS™ cardiac resynchronization therapy defibrillator (CRT-D) and TELIGEN™ implantable cardioverter defibrillator (ICD). These devices represent entirely new platforms to treat heart failure and sudden cardiac death and are the result of a multi-year research and development effort to provide physicians enhanced clinical options for their patients.

"COGNIS and TELIGEN are truly breakthrough technologies featuring significant engineering advances," said Jim Tobin, President and Chief Executive Officer of Boston Scientific. "These products are testaments to the revitalization of our CRM business and our strong product pipeline. With more than 10 worldwide regulatory approvals since the beginning of the year and several others planned, we are delivering enhanced therapy systems designed to meet clinician needs for safety, reliability and better patient outcomes."

"When prescribing a high-energy device, I often had to make trade-offs among device size, battery longevity and features," said Poul-Erik Bloch-Thomson, M.D., KAS Gentofte Hospital, University of Copenhagen, Hellerup, Denmark. "The COGNIS and TELIGEN devices eliminate those trade-offs without compromising therapy options."

The COGNIS CRT-D and the TELIGEN ICD are among the world's smallest and thinnest high-energy devices at 32.5 cc and 31.5 cc respectively, while less than 10 mm thick. Both devices offer features based on substantial engineering advances, including extended battery longevity over previous Company devices, self-correcting software and improved programming technology.

COGNIS and TELIGEN are built on entirely new platforms, including device hardware, software and programming interface. Both devices offer a redundant hardware system called SafetyCore™, which provides lifesaving shock therapy and basic pacing functionality in the unlikely event of a system error. The products employ digital signal processing and are equipped with increased levels of digital memory, enabling more patient data to be captured and used by clinicians.

Key features of the COGNIS CRT-D include:
-- SmartDelay™ -- quickly proposes programmable device settings, which enables physicians to tailor individualized pacing therapy for their patients.

-- Bi-V Trigger -- helps physicians manage heart failure patients with frequent atrial arrhythmias.

-- Electronic Repositioning™ -- provides physicians with six configurations for stimulating the left side of the heart even after implant, which may help avoid an additional surgical procedure.

Key features of the TELIGEN ICD include:
-- Thinnest ICD device available in the world -- the small size and physiologic shape are designed with patient comfort in mind.

-- Quick Convert™ -- provides the ability for patients to receive pacing therapy for ventricular tachycardias.

-- Enhanced AV Search algorithm -- designed to minimize unnecessary right ventricular pacing. This feature, now with an extendable AV delay out to 400 milliseconds, provides physicians with additional flexibility to tailor device programming for individual patient needs.

COGNIS and TELIGEN are designed to be used with the LATITUDE® Patient Management System. The Company intends to offer LATITUDE support for COGNIS and TELIGEN as soon as possible following FDA approval.

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: http://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, regulatory approval of our

products, new product launches, competitive offerings, our growth strategy, and our market position. 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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