

Boston Scientific

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

PRNewswire-FirstCall
NATICK, Mass.
(NYSE:BSX)

NATICK, Mass., Jan. 22 [PRNewswire-FirstCall/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced CE Mark approval for 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.

When choosing a high-energy device, physicians often must make trade-offs among device size, battery longevity and features. The COGNIS CRT-D and the TELIGEN ICD are designed to eliminate those compromises.

They 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 significant engineering advances, including extended battery longevity, self-correcting software and improved programming technology. Both devices also offer SafetyCore™, a feature that in the unlikely event of a system error provides lifesaving shock therapy and basic pacing functionality.

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 device available in the world, designed with patient comfort in mind
- Reverse Mode Switch™: designed to eliminate unnecessary ventricular pacing
- Quick Convert™: provides the ability for patients to receive pacing therapy for ventricular tachycardias

"Our CRM team is refocused on delivering therapy systems that meet clinician needs for safety, reliability and better patient outcomes," said Jim Tobin, President and Chief Executive Officer of Boston Scientific. "We have re-engineered the way we design, build, test and report on our technology. The COGNIS CRT-D and the TELIGEN ICD are testaments to the revitalization of our CRM business and are just two of the many new products we plan to launch in 2008."

The first COGNIS and TELIGEN implants are scheduled to take place early next month. The Company plans to build to a full launch in Europe and other international markets in the second quarter.

The COGNIS CRT-D and the TELIGEN ICD are pending approval by the U.S. Food and Drug Administration and are not available for sale in the United States.

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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