

Boston Scientific

Boston Scientific Announces CE Mark Approval for Next-Generation Cardiac Resynchronization Therapy Defibrillator

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

NATICK, Mass., Dec. 28 [PRNewswire-FirstCall](#)/ -- Boston Scientific Corporation (NYSE: BSX) today announced CE Mark approval for its LIVIAN™ cardiac resynchronization therapy defibrillator (CRT-D), which treats heart failure and helps protect patients at risk of sudden cardiac death. The LIVIAN CRT-D is specifically designed to monitor heartbeats in heart failure patients and deliver small electrical impulses that may improve the heart's pumping ability.

The LIVIAN CRT-D, which is available in high-energy and standard-energy models, enables clinicians to customize therapy based on a patient's individual needs. The implantable device uses Boston Scientific proprietary technology -- built on years of clinical research -- and is designed to improve a patient's response to cardiac resynchronization therapy. LIVIAN also offers clinicians technology to help manage heart failure patients with frequent atrial arrhythmias.

"This next-generation CRT-D offers physicians in Europe and elsewhere even more flexibility for tailoring therapy to each patient," said Jim Tobin, President and Chief Executive Officer of Boston Scientific. "It is a testament to our ongoing commitment to providing innovative solutions for the treatment of heart failure."

Heart failure is a debilitating condition in which the heart weakens and gradually loses the ability to pump blood effectively. Nearly 22 million people worldwide -- including approximately 6.5 million in Europe -- currently suffer from heart failure, which affects not only a patient's quality of life, but also life expectancy. Nearly one million new cases of heart failure are diagnosed annually, making it the most rapidly growing cardiovascular disorder.

This is the first approval of a Boston Scientific-branded cardiac rhythm management device to treat heart failure.

The LIVIAN CRT-D is pending approval by the U.S. Food and Drug Administration and is 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, 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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