Boston Scientific

Boston Scientific Receives FDA Approval of First-in-Class S-ICD® System for Patients at Risk of Sudden Cardiac Arrest

NATICK, Mass., Sept. 28, 2012 /PRNewswire/ -- The U.S. Food and Drug Administration has granted Boston Scientific Corporation (NYSE: BSX) regulatory approval for its S-ICD® System, the world's first and only commercially available subcutaneous implantable defibrillator (S-ICD) for the treatment of patients at risk for sudden cardiac arrest (SCA). The S-ICD System sits entirely just below the skin without the need for thin, insulated wires -- known as electrodes or 'leads' -- to be placed into the heart. This leaves the heart and blood vessels untouched, offering patients an alternative to transvenous implantable cardioverter defibrillators (ICDs), which require leads to be placed in the heart itself.

"The S-ICD System establishes the first new category of cardiac rhythm management devices since the introduction of cardiac resynchronization therapy," said Raul Weiss, M.D., Associate Professor-Clinical, Cardiovascular Medicine at The Ohio State University. "Doctors now have a breakthrough treatment option that provides protection from sudden cardiac arrest without touching the heart."

Approval of the S-ICD System was based on data from a 330-patient, prospective, non-randomized, multicenter clinical study, which evaluated the safety and effectiveness of the system in patients at risk of SCA. The S-ICD System met the primary endpoints of the study, and results were presented earlier this year at the Heart Rhythm Society 33rd Annual Scientific Sessions. The study results support that the S-ICD System is an important new treatment option for a wide range of primary and secondary prevention patients.

"With the addition of the S-ICD System, we believe Boston Scientific has a compelling and highly differentiated portfolio that will help fuel our growth strategy," said Hank Kucheman, chief executive officer, Boston Scientific. "We are the only company to offer an FDA-approved subcutaneous implantable defibrillator and expect this to be the case for several years. The S-ICD System, coupled with our numerous recent regulatory approvals and our other innovative products, such as the WATCHMAN® Left Atrial Appendage Closure Device and Alair® Bronchial Thermoplasty System for the treatment of severe asthma, demonstrates our continued commitment to developing and bringing to market innovative products for physicians and their patients."

Sudden cardiac arrest is an abrupt loss of heart function. Most episodes are caused by the rapid and/or chaotic activity of the heart known as ventricular tachycardia or ventricular fibrillation. Recent estimates show that approximately 850,000 people in the United States are at risk of SCA and indicated for an ICD device, but remain unprotected.

"Each year, thousands of patients indicated for an ICD are not referred to a specialist and remain untreated," said William T. Abraham, MD, FACC, Director, Division of Cardiovascular Medicine at The Ohio State University Heart Center. "The S-ICD System is an important new treatment option that has the potential to improve patient acceptance of ICD therapy."

The S-ICD System is designed to provide the same protection from sudden cardiac arrest as transvenous ICDs. The system has two main components: (1) the pulse generator, which powers the system, monitors heart activity, and delivers a shock if needed, and (2) the electrode, which enables the device to sense the cardiac rhythm and deliver shocks when necessary. Both components are implanted just under the skin—the generator at the side of the chest, and the electrode beside the breastbone. Unlike transvenous ICDs, the heart and blood vessels remain untouched. Implantation with the S-ICD System is straightforward using anatomical landmarks, without the need for fluoroscopy (an x-ray procedure that makes it possible to see internal organs in motion). Fluoroscopy is required for implanting the leads attached to transvenous ICD systems.

Boston Scientific expects to begin a phased launch of the S-ICD System that will expand over time as medical professionals are trained on the safe and effective use of the system. The company acquired the S-ICD System earlier this year when it completed the acquisition of Cameron Health, Inc. The S-ICD System received CE Mark in 2009 and is commercially available in many countries in Europe as well as in New Zealand. To date, more than 1,400 devices have been implanted in patients around the world. To download a high-resolution image of the S-ICD System go to our Image Gallery.

The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

The WATCHMAN device is an investigational device in the United States. It is limited by applicable law to investigational use and not available for sale.

About Boston Scientific
Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices that 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 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 our business plans and growth strategy, markets for our products, regulatory approvals, the importance of the S-ICD System, our technology, clinical trials, product launches, 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, legal and regulatory conditions; clinical trials and outcomes; new product introductions; product performance; demographic trends; intellectual property; litigation; financial market conditions; and future business decisions made by us and our competitors. Such 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.

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