Boston Scientific Announces CE Mark Approval And First Implants Of Its Next-Generation X4 Quadripolar CRT-D Systems

Boston Scientific Corporation (NYSE: BSX) has received CE Mark approval of its X4 line of quadripolar CRT-D systems, including the AUTOGEN™ X4, DYNAGEN™ X4, and INOGEN™ X4 cardiac resynchronization therapy defibrillators (CRT-Ds), a suite of ACUITY™ X4 quadripolar LV leads and the ACUITY™ PRO lead delivery system. The company's latest devices to treat heart failure and sudden cardiac arrest are designed to advance patient care and improve the implant experience.

Heart failure is a chronic, progressive condition in which the heart muscle is unable to pump enough blood to meet the body's needs for blood and oxygen.[1] Sudden cardiac arrest (SCA) is a sudden, unexpected death caused by loss of heart function. SCA is a leading cause of death in Europe, claiming more than 350,000 lives per year.[2]

One of the first implants of the AUTOGEN X4 CRT-Ds was performed by Prof. Antonio Curnis, head of Electrophysiology, Brescia University, Civili Hospital, Brescia, Italy, and Dr. Luca Bontempi, an electrophysiologist in the same unit.

"The unique design of the ACUITY X4 lead allows me to pace from more optimal locations while enabling excellent stability of the lead, low battery consumption and avoiding phrenic nerve stimulation, which are all important issues for CRT patients," said Prof. Curnis. "Thanks to the 17 pacing vector options, it is possible to manage micro dislodgments of the lead and optimize pacing threshold without additional procedures, drastically reducing the risk to patients. This, along with Boston Scientific's outstanding battery technology, delivers a CRT-D system that truly benefits patients over the long term."

The ACUITY X4 suite of quadripolar LV leads are designed with multiple electrode spacing configurations to accommodate individual patient anatomy, including 3D spiral designs to maximize electrode contact with the myocardium and minimize pacing capture thresholds in non-apical locations. These leads also feature multiple fixation options to optimize stability and the industry's smallest lead tip to enable physicians to access vessels unavailable to other quadripolar leads.

The X4 line of quadripolar CRT-Ds offers the largest number of pacing vector options in the industry and helps physicians effectively address high-pacing capture thresholds and phrenic nerve stimulation, a common complication of CRT therapy due to close proximity of the phrenic nerve to the desired pacing location in the left ventricle. The X4 CRT-Ds also feature Boston Scientific's 6-year warranty and industry-leading longevity. An independent, single-center, observational study of 646 CRT-D recipients (n= 173 BSX, 416 MDT, 57 SJM devices) implanted between January 1, 2008 and December 31, 2010 recently published in the United States showed that during 2.7+/-1.5 years follow-up, only four percent of Boston Scientific device batteries had depleted, compared to seven percent from St. Jude Medical and 25 percent from Medtronic.[3] X4 CRT-Ds utilize the same, industry-leading battery capacity and advanced battery chemistry as the Boston Scientific devices used in this study.

Following CE Mark approval of the X4 quadripolar CRT-D systems, Boston Scientific plans to initiate a global clinical trial to gather additional data on ACUITY X4 leads in patients indicated for a CRT-D. This prospective, non-randomized observational study, Maximizing CRT Delivery by Using Multipolar Coronary Sinus Lead Family ACUITY X4 (RALLY X4), is expected to enroll up to 1,000 patients who will receive the ACUITY X4 leads at approximately 100 centers across 18 countries.

"Heart failure is a major cardiovascular problem and CRT-Ds can save lives and improve quality of life. The CE Mark approval of our innovative quadripolar CRT-D systems is truly a milestone when it comes to treating patients with heart failure and at risk of sudden cardiac arrest," said Michael Onuscheck, senior vice president and president, Boston Scientific Europe. "We are also excited to provide physicians with a CRT-D system that can significantly improve the implant experience."

Boston Scientific's X4 quadripolar CRT-D system is currently approved for use in CE Mark countries only. In the US, the X4 quadripolar CRT-D system is an investigational device and not available for sale.

About Boston Scientific
Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 30 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com and connect on Twitter and Facebook.

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 product launches and launch cadence, clinical trials and impact of data, product performance and impact, 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; 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.

1American Heart Association: Link; content was last reviewed on 08/20/2012.

2ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death Europace 2006; 8:746-837.

3Mian Bilal Alam, Muhammad Bilal Munir, Rohit Rattan, Susan Flanigan, Evan Adelstein, Sandeep Jain, and Samir Saba, Battery longevity in cardiac resynchronization therapy implantable cardioverter defibrillators, Europace 2013 : eut301v1-eut301.

---

https://news.bostonscientific.eu/2013-12-17-Boston-Scientific-Announces-CE-Mark-Approval-And-First-Implants-Of-Its-Next-Generation-X4-Quadripolar-CRT-D-Systems