Boston Scientific

Boston Scientific Announces Pacemaker CE Mark With Options For Magnetic Resonance Imaging

The innovative devices allow pacemaker patients access to full body MRI scans in 1.5 Tesla and 3.0 Tesla systems

MARLBOROUGH, Mass., Oct. 16, 2014 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has received CE Mark approval for the ACCOLADE™ pacemaker family. When implanted with the company's INGEVITY™ leads, ACCOLADE pacemakers are the first to enable patients to receive full-body MRI scans in both 1.5 Tesla and 3.0 Tesla systems. In addition, the Boston Scientific ImageReady™ technology offers the most flexible MRI options, allowing higher energy scan sequences, and featuring a programmable MRI timer designed to improve patient workflow.[12345]

The first ACCOLADE device implant was performed by a team coordinated by Prof. Francesco Romeo, Director of the Cardiology Department of Fondazione Policlinico Tor Vergata, Rome, and President-Elect of Italian Society of Cardiology (SIC). "Thanks to the ACCOLADE pacemaker family, I can offer my patients the best pacing therapies while giving them unparalleled access to imaging," said Prof. Romeo. "Additionally, the full suite of diagnostics and the excellent longevity of the device mean that I should be able to utilize the device for my patients undergoing MRI scans in the future – many years from now."

In addition to the CE mark approval and launch of the ACCOLADE pacemaker family, Boston Scientific received CE Mark approval for the VISIONIST™ and VALITUDE™ CRT-Ps with quadripolar pacing technology. When paired with the ACUITY™ X4 pacing leads, these systems offer many options to reach and pace the target location in the left ventricle, potentially improving the patient response to CRT therapy.[6] Dr. Stuart Harris, Clinical Director of the Essex Cardiothoracic Centre, Basildon, UK, performed the first implant of the VISIONIST X4 system.

"We have prioritized investments and now have the first and only subcutaneous ICD, the smallest ICD, and the longest-lasting pacemaker, ICD and CRT devices in the world," said Joe Fitzgerald, executive vice president and president, Rhythm Management. "Now, with the ACCOLADE pacemaker family, we also offer the most flexible MRI conditional pacemaker system, along with advanced diagnostics that assist physicians in detecting atrial arrhythmias. We believe that the provision of automatic daily monitoring and advanced diagnostics to our pacemaker devices will help physicians identify atrial fibrillation sooner, enabling them to initiate patient anti-coagulation therapy to reduce the risk of stroke."

In addition, Boston Scientific is actively pursuing MRI compatibility for our existing implantable cardioverter defibrillators (ICD), cardiac resynchronization therapy defibrillators (CRT-D), including the AUTOGEN™, DYNAGEN™, INOGEN™, and ORIGEN™ CRT-Ds, and lead technologies such as the INGEVITY™, RELIANCE™, and ACUITY™ leads.

The ACCOLADE, VISIONIST, VALITUDE, AUTOGEN, ORIGEN, INGEVITY, and ACUITY X4 devices are not available for sale in the U.S.

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 35 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 us at www.bostonscientific.com. For more information, visit us at www.bostonscientific.com or connect with us on Twitter or 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 new product launches and launch cadence, regulatory approvals, markets for our products 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.

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[1] Boston Scientific: Physician Technical Manual 359250-001 EN Europe 2014-05

[2] MDT ADVISA DR MRI™ SURESCAN™ A3DR01 Clinician Manual M939188A001C 2010-01-28)

[3] St. Jude Medical Accent Model PM1210 Spec Sheet (G0205), Accent Brochure (G0221)

[4] Biotronik: Epyra 8 HF-T, eGA-HW_403588-D Epyra (ProMRI) p. 35

[5] Sorin Kora 100 Implant Manual, 2013-09 U199A

[6] Left Ventricular Lead Position and Clinical Outcome in the Multicenter Automatic Defibrillator Implantation Trial – Cardiac Resynchronization Therapy (MADIT CRT Sub-study)

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