Boston Scientific

Boston Scientific Receives FDA 510(k) Clearance for the LUX-Dx™ Insertable Cardiac Monitor System

First ICM device with remote programming paired with dual-stage arrhythmia detection algorithm

MARLBOROUGH, Mass., June 29, 2020 /PRNewswire/ -- Boston Scientific (NYSE: BSX) has received U.S. Food and Drug Administration (FDA) 510(k) clearance for the LUX-Dx™ Insertable Cardiac Monitor (ICM) System, a new, long-term diagnostic device implanted in patients to detect arrhythmias associated with conditions such as atrial fibrillation (AF), cryptogenic stroke and syncope.

The new LUX-Dx ICM System is designed with a dual-stage algorithm that detects and then verifies potential arrhythmias before an alert is sent to clinicians, thereby providing actionable data for clinical decision-making. Further, the remote programming capabilities of the device via the LATITUDE Clarity™ Data Management System website allow physicians and care teams to adjust event detection settings without requiring an in-person patient appointment, a feature unavailable on any other ICM currently on the market.

"For physicians, receiving accurate monitoring data and having remote access to programming provides the opportunity to operate with more efficiency and confidence," said Kenneth Stein, M.D., senior vice president and chief medical officer, Rhythm Management and Global Health Policy, Boston Scientific. "The LUX-Dx ICM System is designed to provide physicians the ability to accelerate critical clinical decisions and allow them to spend more time focusing on patient outcomes by reviewing monitoring data and catching false positive detections without compromising sensitivity."

The dual-stage algorithm within the LUX-Dx ICM System can be programmed to identify AF, atrial flutter, rhythm pause, bradycardia and tachycardia episodes and allows the device to detect arrhythmias each time established thresholds or parameters are exceeded. An additional level of verification filters is then applied, which was developed to catch false positive detections before an alert is sent. Additionally, after implant, patients are provided with a mobile device preloaded with the MyLUX™ app which connects via Bluetooth® to their ICM device. The app transmits device data daily, or as needed, to the LATITUDE Clarity Data Management System giving physicians and care teams timely access to vital information.

"The LUX-Dx ICM System represents a significant step forward in developing the diagnostic portfolio for Boston Scientific," said Scott Olson, senior vice president and president, Rhythm Management, Boston Scientific. "The addition of this new offering, alongside existing products and services, affirms our commitment to providing meaningful innovations for the detection and treatment of patients with cardiac arrhythmias."

The company will immediately begin a limited market release of the LUX-Dx ICM System in the U.S. with full launch of the product commencing later this year.

Please visit our Electrophysiology Specialties page to learn more about our products.

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 40 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 our business plans and product performance and impact. 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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