Boston Scientific receives CE mark for expanded indication of INGEVITY™+ Pacing Leads to include left bundle branch area pacing

Conduction system pacing technique may promote greater ventricular synchrony and reduce long-term risk of heart failure associated with traditional right ventricular pacing

PARIS, France, 18 September 2025 – Boston Scientific Corporation (NYSE: BSX) has received CE mark approval to expand the indication for its current-generation INGEVITY™+ Pacing Leads – thin wires that are implanted in the heart and connected to a pacemaker. This expansion now includes conduction system pacing (CSP) and sensing of the left bundle branch area (LBBA) of the heart when connected to a single- or dual-chamber pacemaker.

LBBA pacing offers a physiological alternative to traditional right ventricular pacing for patients with symptomatic bradycardia — a condition where the heart beats too slowly. This approach utilises the heart's natural electrical system by placing a lead in the LBBA, which may promote greater ventricular synchrony and potentially reduce the long-term risk of heart failure associated with conventional right ventricular pacing.[1]

"The CE mark expansion enhances the clinical utility of the INGEVITY+ Pacing Lead by supporting its use in the left bundle branch area — an approach backed by compelling real-world and clinical evidence," said Angelo Auricchio, M.D., Ph.D., chief medical officer for Rhythm Management EMEA, Boston Scientific. "Combined with our expanded CSP portfolio, we can deliver a more tailored, physiological pacing solution to meet the evolving needs of physicians and patients."

The expanded indication was supported by a comprehensive body of clinical evidence, including data from more than 1,100 patients in the INSIGHT-LBBA study[2]. This analysis specifically examined INGEVITY+ pacing leads previously implanted for anti-bradycardia pacing in the LBBA, further supplemented by robust bench testing and LATITUDE™ Programming System data.

"This approval represents a significant advancement in cardiac pacing therapy, which enhances our capacity to provide a pacing solution more aligned with the body's natural needs for patients experiencing symptomatic bradycardia," said Dr Bertini, M.D., Ph.D., head of Electrophysiology at University Hospital S. Anna in Ferrara, Italy. "This technology offers the potential for improved left ventricular synchrony and function, which may lead to a reduction in heart failure-related hospitalisation and an overall better quality of life, while allowing hospitals to increase treatment options and contribute to superior patient outcomes."

The INGEVITY+ Pacing Lead is driven by a stylet during lead placement, which supports positioning the device into a desired location within the heart and allows for both continuous pacing and impedance monitoring — key features that can aid appropriate placement and fixation. The expanded indication follows the launch of the Boston Scientific CSP portfolio — inclusive of Helix Locking Tool, and site-selective pacing (SSPC) delivery catheters, which is designed to support the safe and effective placement of the INGEVITY+ Pacing Lead in the LBBA.

More information on the INGEVITY+ Pacing Lead is available here.

About Boston Scientific

Boston Scientific transforms lives through innovative medical technologies that improve the health of patients around the world. As a global medical technology leader for more than 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. Our portfolio of devices and therapies helps physicians diagnose and treat complex cardiovascular, respiratory, digestive, oncological, neurological and urological diseases and conditions. Learn more at **www.bostonscientific.com** and connect on **LinkedIn**.

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, and new and anticipated product approvals and launches. 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; manufacturing, distribution and supply chain disruptions and cost increases; variations in outcomes of ongoing and future clinical trials and market studies; 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, except as required by law. This cautionary statement is applicable to all forward-looking statements contained in this document.

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[1] Sharma P et al. Clinical outcomes of left bundle branch area pacing compared to right ventricular pacing: Results from the Geisinger-Rush Conduction System Pacing Registry. Heart Rhythm. 2021; 19:3-11

[2] Friedman D et al. Performance of an Active FixationStylet-Driven Lead in Left Bundle Branch Area Pacing: Results from INSIGHT-LBBA. Heart Rhythm 2025

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