Boston Scientific

# Boston Scientific receives Japanese regulatory approval for the FARAPULSE™ Pulsed Field Ablation System

MARLBOROUGH, Mass., Sept. 27, 2024 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announced it has received Pharmaceuticals and Medical Device Agency (PMDA) approval in Japan for the FARAPULSE™ Pulsed Field Ablation (PFA) System. The FARAPULSE PFA System, which is indicated for the isolation of pulmonary veins in the treatment of paroxysmal atrial fibrillation (AF), is a novel alternative to standard-of-care thermal ablation treatment.

"The FARAPULSE PFA System is the most clinically studied PFA system and its use in treating more than 125,000 patients globally to date continues to reinforce its strong safety, efficacy and efficiency profile," said Nick Spadea-Anello, president, Electrophysiology, Boston Scientific. "The rapid adoption of the FARAPULSE PFA System, which is now approved in more than 65 countries, indicates a paradigm shift for the treatment of paroxysmal AF – one that has clinical benefits to both physicians and patients – and we look forward to bringing this differentiated technology to Japan."

AF can lead to increased risk of death, stroke and heart failure[1] and affects more than one million people in Japan,[2] while worldwide AF prevalence is conservatively estimated to impact 38 million individuals.[3] Unlike traditional thermal ablation, which uses extreme heat or cold to ablate cardiac tissue associated with AF, the FARAPULSE PFA System uses non-thermal electrical fields that avoid damage to surrounding structures.

"Clinical evidence and extensive real-world use have demonstrated the FARAPULSE PFA System to be an efficient and more predictable procedure than traditional thermal ablation and a proven safe technology," said Kazuhiro Satomi, M.D., Ph.D., professor, Department of Cardiology and director, Heart Rhythm Center, Tokyo Medical University Hospital. "This technology has the potential to rapidly advance clinical practice and improve outcomes and is anticipated to further expand the range of treatment options for AF that can be tailored to each patient's condition."

Adding to its robust body of clinical evidence for the FARAPULSE PFA System, Boston Scientific expects to initiate the OPTION-A clinical trial in Japan, China, Taiwan and Hong Kong in early 2025 to study the safety and efficacy of concomitant procedures using the FARAPULSE PFA System for cardiac ablation and the WATCHMAN FLX™ Pro Left Atrial Appendage Closure Device.

Boston Scientific plans to launch the FARAPULSE PFA System in Japan in the coming weeks, following reimbursement approval. More information on the FARAPULSE PFA System 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 45 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 health care. 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** and **X**, formerly Twitter.

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, clinical trials, and product launches, 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; 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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