Boston Scientific

Boston Scientific receives FDA approval for expanded labeling of FARAPULSE™ Pulsed Field Ablation System

The FARAPULSE PFA System now approved for pulmonary vein and posterior wall ablation in patients with persistent atrial fibrillation

MARLBOROUGH, Mass., July 7, 2025 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has received U.S. Food and Drug Administration (FDA) approval to expand the instructions for use (IFU) labeling for the FARAPULSE™ Pulsed Field Ablation (PFA) System. The updated labeling now includes approval for the system in the treatment of drug refractory, symptomatic persistent atrial fibrillation (AF), an arrythmia in which the heart beats abnormally for at least seven days.

AF affects an estimated 59 million people worldwide and many have the persistent form of the condition, which can cause dizziness, fatigue, shortness of breath and increase the risk of stroke. The FARAPULSE PFA System treats AF by delivering pulsed field energy through a catheter to ablate heart tissue. This approval updates the IFU for both the FARAWAVE™ PFA Catheter and the FARAWAVE NAV™ PFA Catheter to include treatment for patients with persistent AF.

"Backed by clinical evidence and our global commercial experience, this update advances our efforts to further shape the future of AF treatment with safe and effective ablation technologies," said Brad Sutton, M.D., chief medical officer, AF Solutions, Boston Scientific. "We look forward to studying the system in new clinical trials, including patients in need of re-do ablations and those with more complex arrhythmias, which account for a large portion of the procedures today still using thermal ablation."

The FDA approval for expanded labeling was supported by clinical evidence from phase one of the ADVANTAGE AF clinical trial presented at AF Symposium 2025 and recently published in the *Journal of the American College of Cardiology* and met both the primary safety and effectiveness endpoints. In the prospective, single-arm trial, 260 patients who were drug intolerant to at least one Class I/III anti-arrhythmic drug (AAD) were enrolled at 43 global sites. There were no reported incidences of stroke, pulmonary vein stenosis, atrio-esophageal fistula or major access complications and the symptomatic AF recurrence-free rate was 85.3%. Observationally, among physicians that performed three or more procedures, the symptomatic recurrence-free rate increased to 91.4%.

Boston Scientific anticipates CE mark as well as approval inJapan and China in the coming months. The company also recently initiated the ReMATCH IDE clinical trial, which will study approximately 375 patients across 40 centers in the U.S. and Asia. The study will evaluate the safety and effectiveness of the FARAWAVE PFA Catheter for posterior wall ablation and pulmonary vein isolation in patients with persistent AF who previously received an ablation with a PFA, radiofrequency or cryoablation catheter and experienced a recurrence of the condition. It will also evaluate adjunctive use of the FARAPOINT™ PFA Catheter* for cavotricuspid isthmus ablation and left atrial ablation of the mitral isthmus in the same patient population.

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 and product performance and impact, clinical trials, 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: economic conditions, including the impact of foreign currency fluctuations; future U.S. and global political, competitive, reimbursement and regulatory conditions, including changing trade and tariff policies; geopolitical events; manufacturing, distribution and supply chain disruptions and cost increases;

disruptions caused by cybersecurity events; disruptions caused by public health emergencies or extreme weather or other climate change-related events; labor shortages and increases in labor costs; variations in outcomes of ongoing and future clinical trials and market studies; new product introductions; expected procedural volumes; the closing and integration of acquisitions; demographic trends; intellectual property; litigation; financial market conditions; the execution and effect of our business strategy, including our cost-savings and growth initiatives; 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 Linz, Dominik, et al. Atrial fibrillation: epidemiology, screening and digital health. Lancet Reg Health Eur. 2024 Feb 1:37:100786.

*CAUTION: Investigational Device. Limited by Federal (or US) law to investigational use only.

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