Boston Scientific

Boston Scientific Initiates AVANT GUARD Clinical Trial to Evaluate FARAPULSE™ Pulsed Field Ablation System as First-Line Treatment for Persistent Atrial Fibrillation

MARLBOROUGH, Mass., Dec. 28, 2023 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has initiated the AVANT GUARD clinical trial to evaluate the safety and effectiveness of the FARAPULSE™ Pulsed Field Ablation (PFA) System* as a first-line treatment for persistent atrial fibrillation (AF), the only trial to study the use of PFA as frontline therapy in patients with this form of AF. Outcomes of ablation with the FARAPULSE PFA System – a nonthermal treatment in which electric fields selectively ablate heart tissue – will be compared to outcomes following use of anti-arrhythmic drug (AAD) therapy, which is commonly prescribed for patients living with persistent AF.

Unlike paroxysmal AF, which describes symptoms that last for seven days or fewer, persistent AF is a sustained arrhythmia that lasts for more than a week[1]. Early treatment of persistent AF can reduce the risk of blood clots, stroke, and heart failure, and may prevent the disease from becoming permanent. Patients are often treated with AADs as frontline therapy for heart rhythm maintenance, though some can experience adverse effects and limited efficacy. Cardiac ablation is a potential alternative interventional strategy for those living with persistent AF.

"With nearly 40,000 patients treated to date in clinical and commercial settings, the FARAPULSE PFA System continues to demonstrate a promising safety and effectiveness profile, upon which this study seeks to build," said Dr. Brad Sutton, chief medical officer, AF Solutions, Boston Scientific. "The AVANT GUARD trial is exciting in that it has the potential to change clinical practice by advancing the therapy to be utilized as an earlier treatment for persistent AF, which may lead to better long-term outcomes and establish the FARAPULSE PFA System as the preferred method for treating the disease."

The randomized AVANT GUARD trial will enroll more than 500 patients diagnosed with persistent AF at up to 75 sites globally. Patients in the study will be randomized to undergo pulmonary vein isolation (PVI) and left atrial posterior wall ablation using the FARAPULSE PFA System, or receive AAD treatment, and followed for three years. The trial will evaluate the outcomes of therapy provided with the FARAPULSE PFA System versus AADs, including device-or procedure-related adverse events, the rates of freedom from AF, atrial flutter, or atrial tachycardia, as well as AF burden – a measurement of the amount of AF an individual experiences.

All patients in the trial will also be inserted with the Boston Scientific LUX-Dx™ Insertable Cardiac Monitor. This device simplifies the monitoring process for patients by automatically capturing and transmitting arrhythmia episode data, and is designed to detect recurrence of cardiac arrhythmias and assess AF burden by providing continuous rhythm monitoring.

This week, the Cleveland Clinic enrolled the first patient in the AVANT GUARD trial, overseen by Dr. Oussama Wazni, vice chair of cardiovascular medicine and section head, Cardiac Electrophysiology and Pacing, Cleveland Clinic, who is also serving as the lead investigator of the trial.

Earlier this year, clinical trial data presented demonstrated the FARAPULSE PFA System is noninferior to standard-of-care therapies for the treatment of paroxysmal AF, with superior efficiency, while additional real-world data from more than 17,000 patients demonstrated continued real-world safety, efficacy and efficiency of the system. Boston Scientific also completed enrollment in the first phase of the ADVANTAGE AF clinical trial in the third quarter of 2023, which is studying the system for the treatment of patients with drug refractory symptomatic persistent AF, and commenced enrollment in an extension arm of the study to evaluate the safety and effectiveness of adjunctive use of the FARAPOINT™ PFA Catheter for cavotricuspid isthmus (CTI) ablations, a procedure used to treat atrial flutter.

The company now anticipates U.S. Food and Drug Administration approval of the FARAPULSE PFA System in the first quarter of 2024. Additional information about clinical evidence supporting the device can be found here.

*Caution: Investigational Device. Limited by Federal (or US) law to investigational use only. Not available for sale.

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 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, new and anticipated product approvals and launches, and clinical trials. 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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