Boston Scientific

Boston Scientific initiates NAVIGATE-PF study of the FARAWAVE™ Nav Pulsed Field Ablation Catheter and FARAVIEW™ Software Module

Learn about the study of FARAVIEW™ Software Module and FARAWAVE™ Nav Pulsed Field Ablation Catheter for patients with paroxysmal and persistent AFib.

MARLBOROUGH, Mass., April 8, 2024 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has initiated the NAVIGATE-PF study of the FARAVIEW™ Software Module* when it is used to visualize and track the FARAWAVE™ Nav Pulsed Field Ablation (PFA) Catheter* for the treatment of patients with paroxysmal and persistent atrial fibrillation (AF). The FARAVIEW technology and the FARAWAVE Nav catheter expand the capabilities of the FARAPULSE™ PFA System through integration with our cardiac mapping system.

In a pulsed field cardiac ablation procedure, a catheter is guided into the heart to administer targeted non-thermal electrical fields that selectively treat heart tissue cells, while avoiding damage to nearby structures. Before PFA therapy application, a physician might employ a separate cardiac mapping catheter to examine and analyze the heart's electrical patterns to plan the PFA applications. The FARAWAVE Nav PFA Catheter adds magnetic navigation capabilities to the current FARAWAVE PFA catheter, enabling detailed mapping and PFA therapy within the same device. This mapping data is visualized using the new FARAVIEW Software Module, offering a tailored mapping solution for procedures with the FARAPULSE PFA System.

"Creating a detailed cardiac map during an ablation procedure can improve guidance, reduce fluoroscopy times and assist physicians in assessing the location of energy delivered, which may improve patient outcomes," said Ignacio García-Bolao, M.D., Ph.D., study investigator and director of cardiology and cardiovascular surgery, Clinica Universidad de Navarra, Pamplona, Spain. "Through this study, we hope to identify the procedural benefits of the FARAWAVE Nav catheter, which can both map and ablate, alongside technology that allows for magnetically-tracked, dynamic visualization of a patient's cardiac anatomy and catheter configuration."

In the prospective, single-arm, open-label, multi-center NAVIGATE-PF study, approximately 30 patients at several European centers who live with paroxysmal or persistent AF will be enrolled. All patients in the study will have cardiac mapping performed during their procedures. Those living with paroxysmal AF will undergo pulmonary vein isolation, while patients with persistent AF will undergo additional posterior wall isolation at the discretion of the physician performing the procedure.

"This study seeks to build on the compelling performance of the FARAPULSE PFA System by providing an integrated mapping and navigation experience for physicians," said Brad Sutton, M.D., chief medical officer, AF Solutions, Boston Scientific. "Adding navigation and visualization capabilities to this PFA system, which is leading the way in terms of safety, efficacy and efficiency, is an exciting proposition for physicians and patients alike."

Boston Scientific anticipates U.S. regulatory approval of the FARAWAVE NAV PFA Catheter and the FARAVIEW Software Module in the second half of 2024.

More information on the FARAPULSE PFA System is availablehere.

*Caution: Investigational Device. Limited by Federal (or US) law to investigational use only. Not available for sale.
** Dr. Ignacio Garcia-Bolao is a paid consultant of Boston Scientific Corporation. He has not been compensated in connection with this press release.

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 and X, formerly Twitter.

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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; 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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