Boston Scientific

ADVENT Study of the FARAPULSE™ Pulsed Field Ablation System Meets Primary Efficacy and Safety Endpoints

Noninferiority established through high treatment success, low adverse event rates

Findings presented at ESC Congress 2023 and simultaneously published in The New England Journal of Medicine

MARLBOROUGH, Mass. and AMSTERDAM, Aug. 27, 2023 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced positive 12-month results from the pivotal ADVENT clinical trial of the FARAPULSE™ Pulsed Field Ablation (PFA) System*, a nonthermal treatment in which electric fields selectively ablate heart tissue in patients with atrial fibrillation (AF). The study is the first randomized clinical trial to directly compare the efficacy and safety of the FARAPULSE PFA System against standard-of-care ablation – either radiofrequency or cryoablation – for the treatment of patients with paroxysmal, or intermittent, AF. Findings were presented at ESC Congress 2023, the annual meeting of the European Society of Cardiology, and simultaneously published in *The New England Journal of Medicine*.

Data demonstrated the FARAPULSE PFA System was noninferior to standard-of-care therapies, meeting the primary efficacy and safety endpoints, despite the vast majority of physicians having prior experience solely with thermal ablation.** Of note:

- Through 12 months, the single-procedure, off-drug treatment success was 73.3% in the PFA arm of the study and 71.3% in the thermal arm, which met the primary efficacy endpoint.
- The primary composite safety endpoint – defined as acute and chronic device- and procedure-related serious adverse events within seven days of the procedure – was met with a comparably low adverse event rate of 2.1% (six events) in the PFA arm and 1.5% (four events) in the thermal arm.
- Results demonstrated superiority of the FARAPULSE PFA System in the study's secondary safety endpoint with significantly less post-ablation narrowing of the pulmonary veins at three months (0.9%) compared to the thermal ablation arm (12%).
- There were statistically shorter ablation times and less variability with the FARAPULSE PFA System within the PFA arm of the study (mean of 29.2 minutes with a standard deviation of 14.3 minutes) compared to the thermal arm (mean of 50.0 minutes with a standard deviation of 24.6 minutes).

"Excellent overall clinical performance of the FARAPULSE PFA System was seen in this study, particularly the high rate of freedom from atrial arrhythmias and the very low rate of safety events, which is impressive given the rigor of the trial design and monitoring protocols utilized," said Vivek Reddy, M.D., study principal investigator and electrophysiologist at Mount Sinai Hospital, New York. "These highly anticipated findings, together with extensive prior data fromEurope, solidify PFA therapy with this system as a preferred ablative treatment modality."

In this multicenter, prospective and randomized controlled trial, 607 patients in the U.S. with paroxysmal AF who had previously been unsuccessfully treated with at least one anti-arrhythmic drug were enrolled.

"These data underscore the superior procedural efficiency of this novel technology, and real-world use continues to yield strong safety and efficacy outcomes," said Kenneth Stein, M.D., senior vice president and global chief medical officer, Boston Scientific. "The performance of the FARAPULSE PFA System in this trial is an encouraging sign of the potential utilization of the device in the U.S. and we look forward to further studying the system for the treatment of patients with persistent AF in the ADVANTAGE AF clinical trial, which began enrollment earlier this year."

The FARAPULSE PFA System received CE Mark in 2021 and has been used to treat more than 25,000 patients globally to date.

More information on the ADVENT clinical trial is availablehere.

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 clinical trials, our business plans and product approvals, 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; 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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**Caution: Investigational Device. Limited by Federal (or US) law to investigational use only. Not available for sale.*
***ADVENT trial endpoints were analyzed using Bayesian statistical methods.*
****Dr. Vivek Reddy is a paid consultant of Boston Scientific Corporation. He has not been compensated in connection with this press release.*

SOURCE Boston Scientific Corporation

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