Boston Scientific

Boston Scientific Initiates Trial Comparing Left Atrial Appendage Closure to Direct Oral Anticoagulants for Stroke Risk Reduction Post-AFib Ablation

Findings could expand number of patients who can receive alternative treatment to life-long use of blood thinners

MARLBOROUGH, Mass., May 22, 2019 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has initiated the OPTION trial to compare safety and effectiveness of the next-generation WATCHMAN FLX™ left atrial appendage closure (LAAC) platform to first-line oral anticoagulants (OAC) – including direct oral anticoagulants (DOAC) and warfarin – for stroke risk reduction in patients with non-valvular atrial fibrillation (AF) who undergo a cardiac ablation procedure.

Approximately 33 million patients worldwide have AF, a common heart rhythm disorder.[1] In recent years, the number of U.S. patients who have undergone an in-hospital cardiac ablation procedure to prevent abnormal electrical signals from moving through the heart has grown tenfold.[2] More than 50% of those patients become asymptomatic, making them less likely to adhere to current guidelines recommending the continuation of OAC post-procedure to reduce the risk of stroke.[3,4] Stroke is five times more likely to occur in patients with AF than in someone with a normal heart rhythm.[5]

"Cardiac ablation is an effective way to treat an abnormal heart rhythm for many patients, though symptomatic relief can lead these patients to stop taking their blood thinners and unknowingly put themselves at an elevated risk for a stroke," said Dr. Oussama Wazni, co-director of the Ventricular Arrhythmia Center, Center for Atrial Fibrillation and the Atrial Fibrillation Stroke Prevention Center at Cleveland Clinic and the principal investigator for the OPTION trial. "This first-of-its-kind trial will explore whether the one-time WATCHMAN FLX device could replace commonly used anticoagulants for long-term stroke risk reduction in this growing patient population."

The randomized, controlled OPTION trial will enroll 1,600 patients with non-valvular AF who are suitable for OAC therapy and have recently had or will have an ablation. Patients at as many as 130 global sites will be randomized to receive the newest-generation WATCHMAN FLX device or an OAC, inclusive of commonly prescribed DOACs or warfarin. The primary effectiveness endpoint is all cause death, stroke and systemic embolism through 36 months, and the primary safety endpoint is non-procedural bleeding through 36 months.

"Beyond advancing the robust clinical literature supporting the WATCHMAN therapy, findings from the OPTION trial have the potential to expand the number of patients with atrial fibrillation who can receive an alternative to life-long anticoagulants and thus avoid their potential side effects," said Dr. Ian Meredith, AM, executive vice president and global chief medical officer, Boston Scientific. "The unique study design encompasses patients who will receive a WATCHMAN FLX device either after or concurrent to an ablation procedure."

The WATCHMAN device has been implanted in more than 80,000 patients worldwide and the latest-generation WATCHMAN FLX device received CE Mark in March 2019.

In the U.S., the WATCHMAN FLX device is an investigational device and 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 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. 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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