Boston Scientific

Boston Scientific Initiates Trial to Evaluate WATCHMAN FLX™ Left Atrial Appendage Closure Device as First-Line Treatment for People at Risk of Stroke

Trial to study next-generation device as treatment alternative to NOACs for broader population of patients with non-valvular atrial fibrillation

MARLBOROUGH, Mass., Oct. 29, 2020 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has initiated the CHAMPION-AF clinical trial to evaluate the safety and efficacy of the WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device within a broad population of patients with non-valvular atrial fibrillation (NVAF), including those who are at low-to-moderate risk of bleeding from the use of anticoagulation. The device will be compared to treatment with non-vitamin K antagonist oral anticoagulants (NOACs), considered the leading contemporary drugs for stroke risk reduction in this population.

Approximately 33 million people worldwide have AF, a common heart rhythm disorder, which makes them five times more likely to have a stroke than someone with a normal heart rhythm.[1,2] In patients with NVAF, more than 90% of heart-related blood clots form in the left atrial appendage.[3] The WATCHMAN FLX device is designed to close off this area of the heart permanently, providing a one-time solution for those who need an alternative to anticoagulation to reduce their risk of stroke.

The randomized CHAMPION-AF trial will enroll 3,000 patients with NVAF who are suitable for oral anticoagulation therapy across a broad spectrum of stroke and bleeding risk. Patients at approximately 150 global sites will be randomized to receive the newest-generation WATCHMAN FLX device or a NOAC and will be followed for five years. The trial will evaluate the rates of cardiovascular death, stroke, systemic embolism and post-procedural major or clinically relevant non-major bleeding.

"The CHAMPION-AF trial will compare the WATCHMAN FLX device in a head-to-head fashion against best-in-class pharmacological therapy for stroke prevention and evaluate the technology as a first-line therapy for those who can tolerate anticoagulation," said Dr. Ian Meredith, global chief medical officer, Boston Scientific. "A positive outcome for this study has the potential to change clinical practice and expand device access to more patients who would benefit from a one-time procedural alternative to the long-term use of blood thinners and their potential side effects, including those patients at low-to-moderate bleeding risk."

The first patient was enrolled this week by Dr. Devi Nair, director, Cardiac Electrophysiology Division, St. Bernards Heart & Vascular Center. The co-chairs for the trial are Dr. Marty Leon, director, Center for Interventional Vascular Therapy, New York-Presbyterian Heart Valve Center/Columbia University Irving Medical Center; and Dr. Kenneth A. Ellenbogen, chair, Division of Cardiology and Kimmerling professor, Virginia Commonwealth University. Dr. Saibal Kar, physician director, Interventional Cardiology, HCA Healthcare and director, Structural Heart Disease Intervention and Research, Los Robles Health System; and Dr. Shephal Doshi, director, Cardiac Electrophysiology, Pacific Heart Institute and Providence St. John's Health Center, will serve as the principal investigators.

The CHAMPION-AF trial will add to the body of clinical evidence for the WATCHMAN FLX device, along with PINNACLE FLX and the currently-enrolling OPTION trial, a randomized controlled study comparing the device to oral anticoagulants – including but not limited to NOACs – in patients with non-valvular AF who also undergo a cardiac ablation procedure.

The WATCHMAN FLX technology includes new features offering physicians the ability to safely enter, and maneuver within, the left atrial appendage and is the first LAAC device that can be fully recaptured, repositioned and redeployed for precise placement. This next-generation device – which received FDA approval in July 2020 and CE Mark in March 2019 – is also available in broader size options than the previous generation device and can treat a wider range of patient anatomies. The original WATCHMAN device has been implanted in more than 100,000 patients worldwide.

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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[1] Chugh SS, et al. Worldwide epidemiology of atrial fibrillation: a global burden of disease 2010 study. Circulation 2014;129:837–847. doi: https://doi.org/10.1161/CIRCULATIONAHA.113.005119.

[2] Atrial Fibrillation Fact Sheet." Centers for Disease Control and Prevention. http://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_atrial_fibrillation.htm.

[3] Blackshear JL, Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. Ann Thorac Surg. 1996;61:755-759.

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