Boston Scientific

PINNACLE FLX Study of the WATCHMAN FLX™ Left Atrial Appendage Closure Device Presented as Late-Breaking Clinical Trial at HRS 2020 SCIENCE

Trial meets primary safety and efficacy endpoints with low complication rates, 100% effective closure with next-generation stroke risk reduction technology for patients with non-valvular atrial fibrillation

MARLBOROUGH, Mass., May 8, 2020 /PRNewswire/ -- Today, Boston Scientific (NYSE: BSX) announced positive 12-month results from the PINNACLE FLX clinical trial assessing the safety and efficacy of the next-generation WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device for patients with non-valvular atrial fibrillation (NVAF). Presented as a late-breaking clinical trial at HRS 2020 SCIENCE, the study evaluated performance of the WATCHMAN FLX device as an alternative to oral anticoagulation therapy, including non-vitamin K antagonist oral anticoagulants (NOACs), for stroke risk reduction in patients with NVAF.

The prospective, non-randomized PINNACLE FLX trial included 400 patients in the U.S. with NVAF who were eligible for anti-coagulation therapy to reduce the risk of stroke but had an appropriate rationale to seek a non-pharmaceutical alternative. The trial met its primary safety endpoint – defined as occurrence of a major procedure-related complication within 7 days following the procedure or time of hospital discharge, whichever was later – with a low adverse event rate of 0.5%. The study also met its primary effectiveness endpoint, with data demonstrating a 100% rate of effective LAA closure at 12 months post-procedure with peri-device flow $\leq$ 5mm.

"We believe the next-generation WATCHMAN FLX technology contributed to the excellent overall clinical performance seen in this study, notably the very low rate of safety events and high rate of effective closure," said Shephal Doshi, M.D., study co-principal investigator and cardiologist at Pacific Heart Institute at Providence St. John's Health Center, California. "In fact, we saw that 90 percent of patients showed absolutely no detectable leakage around the device at their 12-month follow up, which compares favorably to the rates of peri-device flow observed in the PROTECT-AF and PREVAIL trials with the predicate WATCHMAN device and may translate into improved long-term clinical outcomes."

Data from the trial also demonstrated an implant success rate of 98.8% and that no patients experienced peri-procedural death, device embolization or pericardial effusion requiring cardiac surgery, all of which is favorable in the context of previous clinical studies.[1] In addition, 96.2% of patients were able to discontinue oral anticoagulation following their 45-day follow up. Secondary endpoints from the PINNACLE FLX study, including the occurrence of ischemic stroke or systemic embolism, will be reported after 24 months of patient follow-up.

"As we have seen in previous clinical trials, WATCHMAN technology is well-established as a safe and effective therapeutic option for patients with NVAF at increased risk for stroke and systemic embolism who need an alternative to a lifetime on anti-coagulant medications," said Dr. Ian Meredith, AM, global chief medical officer, Boston Scientific. "We are pleased with the performance exhibited by the next-generation WATCHMAN FLX device in the PINNACLE FLX study, which mirrors positive European physician experience to date and underscores our commitment to advancing this technology for safe treatment of a broader population of eligible patients with NVAF."

The next-generation WATCHMAN FLX device received CE Mark in March 2019 and is designed to advance procedural performance and safety while expanding the treatable population of patients with NVAF. The new frame allows for optimal device engagement with the tissue for long-term stability and a faster, complete seal of the LAA. Its fully rounded design also offers physicians the ability to safely enter, and maneuver within, the LAA and to fully recapture, reposition and redeploy the device during the procedure. The WATCHMAN FLX device is available in broader size options to treat a wide range of patient anatomies.

The company plans to further evaluate the WATCHMAN FLX device for patients with NVAF via continued enrollment in the ongoing OPTION trial – comparing the device to oral anticoagulants in patients who also undergo a cardiac ablation procedure – as well as in the CHAMPION-AF clinical trial, which will study a broader anticoagulant-eligible patient population to evaluate the device against NOACs for embolic stroke prevention.

For more information on the WATCHMAN device, visit www.watchman.com.

*The WATCHMAN FLX LAAC Device is an investigational device in the U.S. and not available for sale.

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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.

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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, clinical trials 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] Reddy VY, Holmes DR, et al. JACC 2017; 69(3): 253-261.

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