Boston Scientific

Five-year Follow-up Data Demonstrate the WATCHMAN™ Left Atrial Appendage Closure Device Provides Stroke Risk Reduction Comparable to Warfarin Therapy

Late-breaking Clinical Trial Data Presented at TCT 2017 with Simultaneous Publication in the Journal of the American College of Cardiology

DENVER and MARLBOROUGH, Mass., Nov. 2, 2017 /PRNewswire/ -- Boston Scientific (NYSE: BSX) announced final five-year outcomes data from the PREVAIL study of the WATCHMAN™ Left Atrial Appendage Closure (LAAC) Device today during a late-breaking clinical trial session at the 29th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation, in Denver. The PREVAIL data, combined with final five-year outcomes from the PROTECT-AF clinical trial, demonstrated the WATCHMAN device continues to be a safe and effective alternative to long-term warfarin therapy offering comparable stroke risk reduction for patients with non-valvular atrial fibrillation (AF). The study was also published online today in the *Journal of the American College of Cardiology*.

In the PREVAIL and PROTECT-AF randomized clinical trials, LAAC with the WATCHMAN device was compared to warfarin for stroke prevention in high-risk patients with non-valvular AF. Upon completion of five-year follow up in both trials, study authors conducted a meta-analysis combining all data from the 1,114 randomized patients for a total of 4,343 patient-years. In addition to stroke prevention comparable to warfarin, the analysis concluded the WATCHMAN device also effectively reduced non-procedure related major bleeding, disabling or fatal stroke, and mortality.

"With complete five-year follow up in two randomized clinical trials, left atrial appendage closure with the WATCHMAN device continues to demonstrate statistically significant reductions in death," said Vivek Reddy, M.D., principal investigator and director of Cardiac Arrhythmia Services for The Mount Sinai Hospital and the Mount Sinai Health System. "Importantly, the data further prove the WATCHMAN device is a safe and effective therapeutic alternative for stroke prevention in appropriate patients, enabling them to stop taking warfarin."

The comprehensive analysis confirmed a 55% reduction in disabling or fatal stroke, largely driven by an 80% statistically significant reduction in hemorrhagic stroke. Further, the combined data demonstrated a 52% decrease in non-procedure related major bleeding and 27% reduction in all-cause mortality when compared to long-term warfarin therapy.

"The data presented today lend additional credence to the long-term safety and efficacy for the WATCHMAN device," said Kenneth Stein, M.D., senior vice president and chief medical officer, Rhythm Management and Global Health Policy, Boston Scientific. "The totality of the data from both randomized trials and observational studies convincingly demonstrates ischemic stroke reduction similar to that observed with warfarin, when accounting for differences in CHA_2DS_2-VASc score."

The WATCHMAN device continues to be observed in post-market studies, including the national LAAO Registry™ sponsored by the American College of Cardiology. The registry will capture post-approval data on left atrial appendage occlusion procedures, as outlined as a condition of coverage by the Centers for Medicare and Medicaid Services in the LAAC National Coverage Determination.

For more information on the WATCHMAN device, visitwww.watchman.com.

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 35 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.

CONTACTS:
Trish Backes
Media Relations
(651) 582-5887 (office)
Trish.Backes@bsci.com

Susie Lisa, CFA
Investor Relations
(508) 683-5565 (office)
investor_relations@bsci.com

SOURCE Boston Scientific Corporation

---

https://news.bostonscientific.com/2017-11-02-Five-year-Follow-up-Data-Demonstrate-the-WATCHMAN-TM-Left-Atrial-Appendage-Closure-Device-Provides-Stroke-Risk-Reduction-Comparable-to-Warfarin-Therapy