Boston Scientific

Boston Scientific Announces Initial U.S. Commercial Performance Of The WATCHMAN™ Left Atrial Appendage Closure Device

Late-Breaking Trial Data Presented at TCT Scientific Sessions and Simultaneously Published in the Journal of the American College of Cardiology

WASHINGTON and MARLBOROUGH, Mass., Nov. 2, 2016 /PRNewswire/ -- Boston Scientific (NYSE: BSX) announced initial U.S. commercial performance results of the WATCHMAN™ Left Atrial Appendage Closure (LAAC) Device today during a late-breaking clinical trial session at the 28th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation, in Washington, D.C. Data demonstrated a high rate of procedural success and low rate of complications for the device which offers stroke risk reduction for patients with non-valvular atrial fibrillation (AF) who are seeking an alternative to long-term warfarin therapy. The study was also published online today in the *Journal of the American College of Cardiology*.

In advance of a formal national clinical registry becoming available, procedural data were collected via WATCHMAN clinical specialists during 3,822 consecutive LAAC procedures performed between March 2015 and May 2016 by 382 operating physicians at 169 U.S. medical centers. In this case series, there was a 95.6% implant success rate with a median procedure time of 50 minutes.

Half of the procedures were performed by new implanting physicians without previous experience with the device. Nevertheless, the overall rate of complications evaluated within these data was low at 1.63%, and compared favorably to the clinical trial data leading to device approval, validating the rigorous process for selecting and training new operators. Pericardial tamponade requiring intervention was the most frequent major procedural complication, which was seen in 1.02% of patients. In an additional 0.29% of patients, a hemodynamically insignificant pericardial effusion was observed that did not require intervention. Device embolization, procedure-related stroke and mortality rates also remained low at 0.24%, 0.08% and 0.08%, respectively.

"The 'real-world' data collected from this study indicate high procedural success, even with the large number of new implanting physicians performing one-half of the procedures," said Vivek Reddy, M.D., co-principal investigator and director of Cardiac Arrhythmia Services for The Mount Sinai Hospital and the Mount Sinai Health System. "More importantly, we confirmed the safety of this therapy as evidenced by the low rate of complications."

"This evaluation includes the largest WATCHMAN device patient population studied to date and demonstrated low and consistent complication rates compared to those seen in previous clinical trials," said David R. Holmes, M.D., co-principal investigator and professor of medicine at Mayo Clinic College of Medicine and a consultant in the Division of Cardiovascular Diseases and the Department of Internal Medicine at Mayo Clinic in Rochester, Minnesota. "This provides important procedural insights in the absence of an official Centers for Medicare and Medicaid Services registry being available to collect data immediately following device approval by the U.S. Food and Drug Administration in March, 2015."

The formal national registry capturing data on left atrial appendage occlusion (LAAO) procedures – the LAAO Registry, sponsored by the American College of Cardiology – was approved in August, 2016 by the Centers for Medicare and Medicaid Services. Participation in the registry is a condition of coverage as outlined in the LAAC National Coverage Determination (NCD). The NCD was effective February 8, 2016 and fully implemented nationwide on October 3, 2016.

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.

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