New Four-Year Data From Boston Scientific Demonstrated WATCHMAN™ Device Was Superior To Warfarin For Mortality And Primary Efficacy In Patients With Atrial Fibrillation In Long Term Follow-Up Of The PROTECT AF Trial

Boston Scientific Corporation (NYSE: BSX) reports that the four-year follow-up data from the PROTECT AF clinical trial demonstrated the WATCHMAN® Left Atrial Appendage (LAA) Closure device was statistically superior to warfarin for preventing cardiovascular death, all-cause stroke and systemic embolization. The data demonstrated significant reductions in both cardiovascular and all death compared to warfarin. The data were presented today as a late-breaking clinical trial at Heart Rhythm 2013, the Heart Rhythm Society's 34th Annual Scientific Sessions in Denver, by Vivek Reddy, M.D., a principal investigator of the PROTECT AF trial, and Professor of Medicine and Director of the Cardiac Arrhythmia Services at Mount Sinai School of Medicine in New York. The abstract is titled, "Long Term Results of PROTECT AF: The Mortality Effects of Left Atrial Appendage Closure versus Warfarin for Stroke Prophylaxis in AF."

Atrial fibrillation (AF) is an irregular heartbeat that can lead to blood clots, stroke, heart failure and other heart-related complications. The condition affects approximately 2.7 million Americans and 15 million people worldwide, and is the most common cause of disabling stroke. A primary treatment goal for AF patients is to reduce the risk of blood clots causing stroke. Patients with AF and additional risk factors for stroke are commonly prescribed blood thinning medications, also known as anticoagulants, like warfarin, to prevent blood clots from forming in the heart. However, due to blood monitoring requirements, dietary restrictions, side effects and an increased risk of serious bleeding, many patients are unable or unwilling to take these medications for long periods of time. In contrast, the WATCHMAN device is designed to close off the LAA, a major source of clots in patients with AF, and reduce the risk of stroke, potentially eliminating the need for long term use of blood-thinning medications.

"This is a significant development because for the first time we were able to demonstrate that the WATCHMAN device was superior to warfarin for both primary efficacy and also mortality," said Dr. Reddy. "This has tremendous upside potential for patients. In the PROTECT AF trial, LAA closure with the WATCHMAN device demonstrated the potential for a device-based approach to reduce the risk of stroke in AF patients. As clinicians, we often feel uncomfortable with life-long systemic anticoagulation therapy in patients because of an increased risk of falls and bleeding. The four-year data provide additional support for LAA closure as a potential viable long-term alternative to chronic warfarin therapy for patients to reduce the risk of stroke."

The PROTECT AF clinical trial is a multicenter, prospective randomized clinical trial designed to demonstrate the safety and effectiveness of the Boston Scientific WATCHMAN device in patients with non-valvular AF who are eligible for warfarin therapy and meet certain stroke risk factors. A total of 707 patients from 59 centers were randomized 2:1 to device or warfarin control.

Results
The PROTECT AF trial achieved superiority for the combined endpoint of all stroke, cardiovascular or unexplained death and systemic embolism.[1]

The observed primary efficacy event rate was 2.3 percent and 3.8 percent in the WATCHMAN and control groups, respectively, demonstrating a 40 percent relative risk reduction in primary efficacy in the WATCHMAN group (RR = 0.60, posterior probability of superiority = 96 percent).

Secondary analysis also showed a relative risk reduction and superiority to control for all-cause mortality and cardiovascular mortality.

All-Cause Mortality: the WATCHMAN group was superior to the control group, 3.2 percent to 4.8 percent respectively, representing a 34 percent relative risk reduction in all-cause mortality in the WATCHMAN group (HR = 0.66, p=0.0379).

Cardiovascular Mortality: the WATCHMAN group was superior to the control group, 1.0 percent and 2.4 percent respectively, representing a 60 percent relative risk reduction in cardiovascular death in the WATCHMAN group (HR = 0.40, p=0.0045).

"This is exciting news for patients with non-valvular AF and a high risk of stroke," said Kenneth Stein, M.D., chief medical officer, Cardiac Rhythm Management, Boston Scientific. "These data convincingly show that the WATCHMAN device was superior to the current standard of care in these patients and demonstrated its potential to prevent stroke and save lives. The WATCHMAN device underscores the Boston Scientific commitment to meaningful innovation and to providing the medical community with the tools it needs to improve patients' lives."

About WATCHMAN
PROTECT AF long term data add to the growing body of evidence for the WATCHMAN device as the most studied LAA closure device and the only LAA closure device with long term follow-up. Data from the PROTECT AF trial, PREVAIL study, the WATCHMAN Pilot study six-year data, the ASAP study and the CAP registry data will form the basis for the full and final clinical module to support device regulatory approval in the United States. To date, more than 2,000 patients with 4,800 patient-years of follow-up have been studied in clinical trials of the WATCHMAN device.

The WATCHMAN device was approved for sale in Europe in 2005 and some countries in Asia in 2009. It is already commercially available in 55 countries worldwide. In the United States, the WATCHMAN device is an investigational device, limited by applicable law to investigational use and not available for sale. The device was developed by Atritech, which Boston Scientific acquired in March 2011. Please visit https://www.bostonscientific.com/watchman for more information.

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, markets for our products, clinical trials and the importance of trial results, product performance and impact, and competitive offerings. 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.

REFERENCES 1For Bayesian analysis, posterior probabilities are used to determine superiority; > 95% represents superiority

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https://news.bostonscientific.eu/2013-05-09-New-Four-Year-Data-From-Boston-Scientific-Demonstrated-WATCHMAN-TM-Device-Was-Superior-To-Warfarin-For-Mortality-And-Primary-Efficacy-In-Patients-With-Atrial-Fibrillation-In-Long-Term-Follow-Up-Of-The-PROTECT-AF-Trial