FDA Advisory Committee Panel Votes In Favour of the WATCHMAN™ Device

Comprehensive Clinical Data from Randomized Trials Reviewed

After reviewing updated data and analysis for the Boston Scientific Corporation (NYSE: BSX) WATCHMAN™ Left Atrial Appendage Closure (LAAC) Device, the U.S. Food and Drug Administration (FDA) Circulatory System Devices Panel of the Medical Devices Advisory Committee voted in favor of the Device. By a vote of 6 to 5 (with 1 abstention) the Panel concluded that the benefits of the WATCHMAN Device outweigh the potential risks. Furthermore, the Panel voted that there is reasonable assurance that the Device is safe (12 yes to 0 no). On the question of reasonable assurance of effectiveness, the Panel vote was unfavorable (6 yes to 7 no). The Panel provided substantial input and guidance related to the proposed Indications for Use and target patient population. There was widespread agreement among the Panel members that the Device provides a much needed alternative to long-term anticoagulation for some patients. While not bound by this vote, the FDA takes Advisory Panel comments and recommendations into account when reviewing the WATCHMAN Device application. The company is committed to working with the FDA to address the Panel's comments.

"There is a strong clinical need for a proven device alternative to long-term warfarin therapy for my high stroke risk patients with non-valvular atrial fibrillation," said Vivek Reddy, M.D., Director of the Cardiac Arrhythmia Service at Mount Sinai Medical Center and co-principal investigator of the PROTECT AF and PREVAIL studies. "I'm encouraged that the Panel recognized the importance of having the WATCHMAN Device as an option for appropriate patients."

The Committee's positive vote followed a review of the most recent clinical data and analysis from two randomized control trials, PROTECT AF and PREVAIL, as well as from the CAP (Continued Access Protocol) and CAP2 registries. The WATCHMAN Device is the most studied left atrial appendage closure device and the only one with long-term clinical data from over 2,400 patients and nearly 6,000 patient-years of follow-up in clinical studies. The WATCHMAN Device was approved for sale in Europe in 2005 and is currently approved in more than 70 countries across the globe. In the U.S., the WATCHMAN Device is an investigational device, limited to investigational use and not available for sale.

"Today's recommendation by the Panel is another step toward making this innovative technology available to high risk patients with non-valvular atrial fibrillation who are eligible for warfarin, but who have reasons to seek an alternative to long-term therapy," said Kenneth Stein, M.D., Chief Medical Officer, Rhythm Management, Boston Scientific. "We continue to believe that the totality of the data for the WATCHMAN Device provide reasonable assurance of its safety and efficacy as a treatment alternative for these patients. We look forward to our ongoing discussions with FDA."

About Atrial Fibrillation and Stroke
Atrial fibrillation (AF) is an irregular heartbeat that can lead to blood clots, stroke, heart failure and other heart-related complications. AF is the most common cardiac arrhythmia, currently affecting more than five million Americans.[1] Patients with AF have a five-fold increased risk of stroke due to blood stagnating from the improperly beating atrium and the resulting blood clot formation.[2] Twenty percent of all strokes occur in patients with AF.[3] Stroke is more severe for patients with AF, as they have a seventy percent chance of death or permanent disability.[4]

The most common treatment to reduce the risk of stroke prevention in patients with AF is anticoagulant ("blood-thinning") therapy with warfarin. Despite its proven efficacy, long-term warfarin therapy may be poorly tolerated by some patients and carries a significant risk for bleeding complications.

About the WATCHMAN LAAC Device
The WATCHMAN Device is a catheter-delivered heart implant designed to close the left atrial appendage (LAA) in order to prevent the migration of blood clots from the LAA, and thus, reduce the incidence of stroke and systemic embolism for higher risk patients with non-valvular AF. The LAA is a thin, sack-like appendix arising from the heart and is believed to be the source of a majority of stroke-causing blood clots in people with AF.[4] The WATCHMAN Device is commercially approved in more than 70 countries, with more than 9,000 implants performed worldwide. The device was developed by Atritech, which Boston Scientific acquired in March 2011.

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.

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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 regulatory approvals, markets for our products, clinical trials and impact of data, 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 1Colilla et al., Am J Cardiol. 2013; 112:1142-1147

2Holmes DR, Seminars in Neurology 2010; 30:528–536

3Hart RG, Halperin JL., Ann Intern Med. 1999; 131:688–695

4Blackshear J. and Odell J., Annals of Thoracic Surgery. 1996; 61:755-759
