Boston Scientific

Boston Scientific Announces First U.S. Commercial Procedures With The WATCHMAN™ Left Atrial Appendage Closure Device

Novel Stroke Risk Reduction Option for Indicated Patients with Atrial Fibrillation

MARLBOROUGH, Mass., March 24, 2015 /PRNewswire/ -- This week, four patients in the United States received the first implants of the Boston Scientific Corporation (NYSE: BSX) WATCHMAN™ Left Atrial Appendage Closure (LAAC) Device. The WATCHMAN Device offers a novel stroke risk reduction option for high-risk patients with non-valvular atrial fibrillation (AF) who are seeking an alternative to long-term warfarin therapy. The WATCHMAN Device received U.S. Food and Drug Administration (FDA) approval on Friday, March 13, 2015.

The first WATCHMAN Device procedures in the U.S. were performed by Shephal K. Doshi, M.D., director of Cardiac Electrophysiology and Pacing at Saint John's Health Center in Santa Monica, CA, and Saibal Kar, M.D., director of the Cardiovascular Intervention Center Research at Cedars-Sinai Hospital in Los Angeles, CA.

"With today's successful implantations of the WATCHMAN Device, we are changing the way we deal with stroke risk in high-risk patients with non-valvular atrial fibrillation," said Kar. "For indicated patients like those who received an implant this week, the WATCHMAN Device reduces the risk of stroke, without the need for long-term anticoagulation therapy and its subsequent bleeding risks."

More than five million Americans suffer from an irregular heartbeat called non-valvular atrial fibrillation[i]. Many of these patients are at increased risk of stroke, but as many as 40 percent of those patients eligible for oral anticoagulant therapy do not take this medication[ii] and may need a treatment alternative.

"As physicians, we are always looking for new therapies to satisfy unmet patient needs," said Doshi. "There are many patients like the ones we treated this week with the WATCHMAN Device who are suitable for warfarin, but are not ideal candidates for chronic anticoagulant use. These patients now have a new, proven option to reduce their risk of AF-related stroke."

The WATCHMAN Device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who are at increased risk for stroke and systemic embolism based on $CHADS_2$ or CHA_2DS_2-VASc scores, are deemed by their physicians to be suitable for warfarin, and have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.

"Boston Scientific is proud to work with physicians in making a meaningful impact on patient lives by bringing left atrial appendage closure therapy to the United States," said Kenneth Stein, M.D., chief medical officer, Rhythm Management, Boston Scientific.

The WATCHMAN Device was approved by the FDA based on a robust clinical program, which has now included more than 3,300 patients with 6,000 patient-years of follow-up to date. The WATCHMAN clinical program provides strong evidence that the WATCHMAN Device can be implanted safely and reduces the risk of stroke in eligible patients while enabling most patients to discontinue warfarin.[iii]

Additionally, a meta-analysis of all of the randomized trial data demonstrated that while ischemic stroke reduction favored warfarin, the WATCHMAN Device provided patients with a comparable protection against all-cause stroke and statistically superior reductions in hemorrhagic stroke, disabling stroke, and cardiovascular death compared to warfarin over long-term follow-up.[iii]

The WATCHMAN LAAC Device has been commercially available internationally since 2009. It is registered in 75 countries and more than 10,000 patients have been treated with the WATCHMAN Device.

About Atrial Fibrillation and Stroke

Non-valvular 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.[i] 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.[iv] Twenty percent of all strokes occur in patients with AF.[v] Stroke is more severe for patients with AF, as they have a seventy percent chance of death or permanent disability.[vi]

The most common treatment for stroke risk reduction in patients with AF is blood-thinning warfarin therapy. Despite its proven efficacy, long-term warfarin is not well-tolerated by some patients due to a significant risk for bleeding complications, and numerous quality-of-life tradeoffs, including dietary restrictions and regular blood monitoring.

About the WATCHMAN LAAC Device

The WATCHMAN LAAC 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 >90% of stroke-causing clots that come from the left atrium in people with non-valvular AF. Images of the WATCHMAN Device are available at http://bostonscientific.mediaroom.com/image-gallery?mode=gallery&cat=1760.

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 products, markets for our products, 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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