Boston Scientific

Boston Scientific Receives FDA Approval for WATCHMAN™ Left Atrial Appendage Closure Device

First-Of-Its-Kind Alternative to Long-Term Warfarin Therapy for Stroke Risk Reduction in Patients with Non-Valvular Atrial Fibrillation

MARLBOROUGH, Mass., March 13, 2015 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has received U.S. Food and Drug Administration (FDA) approval for the WATCHMAN Left Atrial Appendage Closure Device. The WATCHMAN Device offers a new stroke risk reduction option for high-risk patients with non-valvular atrial fibrillation who are seeking an alternative to long-term warfarin therapy. The WATCHMAN Device will be made available to U.S. centers involved in our clinical studies and additional, specialized centers as physicians are trained on the implant procedure.

Experience the interactive Multimedia News Release here:http://www.multivu.com/players/English/7223452-boston-scientific-watchman-fda-approval

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.

"The WATCHMAN Device is an important step forward in stroke management for patients with AF," saidVivek Reddy, M.D., Director of the Cardiac Arrhythmia Service at the Mount Sinai Hospital and co-principal investigator of the PROTECT AF and PREVAIL studies. "We know that up to 40 percent of patients who are eligible for oral anticoagulation do not take it for numerous reasons[1], highlighting the need for additional treatment options. The WATCHMAN Device is a breakthrough treatment providing those patients who are suitable for warfarin with an implant-based alternative to long-term warfarin therapy while still reducing the risk of stroke."

The FDA approval of the WATCHMAN Device is based on the robust WATCHMAN clinical program which consists of numerous studies, with more than 2,400 patients and nearly 6,000 patient-years of follow-up. The WATCHMAN clinical program provided strong evidence that the WATCHMAN Device can be implanted safely[2] and reduces the risk of stroke in eligible patients while enabling most patients to discontinue warfarin[3]. 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.[4]

"Today marks a defining moment in the company's journey towards establishing left atrial appendage closure therapy in the United States. Boston Scientific is proud to offer this potentially life-changing stroke risk treatment option to high-risk patients with AF who have a reason to seek a non-drug alternative to warfarin. This therapy could free them from the challenges of long-term warfarin therapy," said Joe Fitzgerald, executive vice president and president, Rhythm Management, Boston Scientific. "FDA approval of the WATCHMAN Device is another example of Boston Scientific delivering on its commitment to bring meaningful innovations to patient care."

The WATCHMAN Device has been commercially available internationally since 2009 and is the leading device in percutaneous left atrial appendage closure globally. It is registered in 75 countries and more than 10,000 patients have been treated with the WATCHMAN Device.

Investor Event and Webcast Information
Boston Scientific, in connection with its attendance at the 2015 American College of Cardiology 64th Annual Scientific Session in San Diego, CA, will host an investor event and live webcast to discuss the WATCHMAN Device on Sunday, March 15. The event, which will include a question and answer session, is scheduled to begin at 1:00 p.m. PT and adjourn at approximately 2:30 p.m. PT and will be hosted by Joe Fitzgerald, executive vice president and president, Rhythm Management, and Kenneth Stein, M.D., senior vice president and chief medical officer, Rhythm Management.Vivek Reddy, M.D., Director of the Cardiac Arrhythmia Service at the Mount Sinai Medical Center will also present.

A live webcast of the event will be available via the Boston Scientific website. Webcast registration is available on the Investor Relations section of the website at www.bostonscientific.com/investors. Registration at least 15 minutes prior to the scheduled start time is encouraged to ensure a timely connection.

A replay of the webcast will be archived and accessible atwww.bostonscientific.com/investors approximately one hour following the completion of the conference call.

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.[5] 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.[6] Twenty percent of all strokes occur in patients with AF.[7] Stroke is more severe for patients with AF, as they have a 70 percent chance of death or permanent disability.[8]

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

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 percent of stroke-causing clots that come from the left atrium in patients with non-valvular AF.[4] 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, our business plans, product launches and availability, clinical trials and data impact, competitive offerings, 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
Media:
Nisha Deo
508-683-5571 (office)
408-893-9243 (cell)
Media Relations
Boston Scientific Corporation
Nisha.deo@bsci.com

Investors:
Susie Lisa, CFA
508-652-5345 (office)
Investor Relations
Boston Scientific Corporation
investor_relations@bsci.com

[1] NCDR Pinnacle Registry
[2] PROTECT AF, CAP, PREVAIL and CAP2
[3] PROTECT AF, CAP, PREVAIL
[4] POOLED PROTECT AF and PREVAIL data
[5] Colilla et al., Am J Cardiol. 2013; 112:1142-1147
[6] Holmes DR, Seminars in Neurology 2010; 30:528–536
[7] Hart RG, Halperin JL., Ann Intern Med. 1999; 131:688–695
[8] Blackshear J. and Odell J., Annals of Thoracic Surgery. 1996; 61:755-759

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/boston-scientific-receives-fda-approval-for-watchman-left-atrial-appendage-closure-device-300050512.html

SOURCE Boston Scientific Corporation

---

https://news.bostonscientific.com/2015-03-13-Boston-Scientific-Receives-FDA-Approval-for-WATCHMAN-Left-Atrial-Appendage-Closure-Device