Boston Scientific

Boston Scientific Receives CE Mark For Next Generation WATCHMAN FLX™ Left Atrial Appendage Closure Device

First Implants Occur in Europe, Commencing Limited Market Release

MARLBOROUGH, Mass., Nov. 19, 2015 /PRNewswire/ -- Boston Scientific (NYSE: BSX) today announced that the first implants of the WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device – the latest generation of the WATCHMAN Device – occurred in Europe following CE mark approval.

"The WATCHMAN Device is the most studied left atrial appendage closure device and has been used to help reduce the risk of stroke for tens of thousands of high-risk patients with non-valvular atrial fibrillation who seek an alternative to long-term anticoagulant therapy," said Dr. Kenneth Stein, chief medical officer, Rhythm Management, Boston Scientific. "We are pleased that this next-generation technology has been granted European regulatory approval and we can begin a controlled product roll-out to clinicians throughout Europe."

WATCHMAN FLX Device implants were performed last week by Dr. Horst Sievert, department head of Cardiology and Vascular Medicine, Sankt Katharinen Hospital, in Frankfurt, Germany; by Dr. Vivek Reddy, director of Cardiac Arrhythmia Services for The Mount Sinai Hospital, at Na Homolce Hospital in Prague, Czech Republic; and Dr. Saibal Kar, director of Cardiovascular Intervention Center Research at Cedars-Sinai Heart Institute, at MC Medicor in Izola, Slovenia.

"The closed-end design of the WATCHMAN FLX Device and the ability to fully recapture and reposition this device make it a very promising option for treating indicated patients with simple to the most complex anatomies," said Dr. Sievert. "With nearly a decade of experience implanting the original WATCHMAN Device, it has been exciting to see the advancements of this technology from Boston Scientific and take part in the first implants of this device in Europe."

The first-generation WATCHMAN Device was CE-marked in 2005 to prevent thrombus embolization from the left atrial appendage (LAA) and reduce the risk of life-threatening bleeding events in patients with non-valvular atrial fibrillation (AF) who are eligible for anticoagulation therapy, and in 2012 the CE Mark indication was expanded to include those who have a contraindication to anticoagulation therapy. AF affects approximately 15 million patients worldwide and is a disorder that disrupts the ability of the heart to beat regularly and pump blood efficiently. Patients with AF have an increased risk of stroke due to the migration of clots formed in the LAA.

This approval marks the second significant regulatory and commercial milestone for the Structural Heart business of Boston Scientific this year, following the U.S. Food and Drug Administration (FDA) approval of the first-generation WATCHMAN Device in March, 2015. In the U.S., 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 CHADS2 or CHA2DS2-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.

Commercialization of the WATCHMAN FLX Device is currently in a limited market release and will become more widely available to approved EU countries in the first half of 2016. The WATCHMAN FLX Device is not available for sale in the U.S.

About the WATCHMAN FLX LAAC Device

The WATCHMAN FLX 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, sac-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 and the WATCHMAN FLX Device are available at http://news.bostonscientific.com/image-gallery.

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, 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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