Boston Scientific

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

Company begins limited market release in Europe

MARLBOROUGH, Mass., March 13, 2019 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announced it has received CE Mark and initiated a limited market release of the next generation WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device in Europe.

Patients with AF are five times more likely to suffer a stroke than someone with a normal heart rhythm.[1] In people with non-valvular atrial fibrillation (AF), data suggests that more than 90% of stroke-causing blood clots that come from the heart are formed in the left atrial appendage.[2] The WATCHMAN left atrial appendage occlusion devices are intended to reduce the risk of stroke in people with non-valvular AF.

"The WATCHMAN device has been implanted in more than 75,000 patients worldwide and we are pleased that this next-generation technology has been granted European regulatory approval so that we can offer it to patients and clinicians throughout Europe," said Kevin Ballinger, president, Interventional Cardiology, Boston Scientific. "The robust clinical evidence and successful commercial outcomes of the WATCHMAN device to-date reinforce the value of this procedure for all appropriate patients."

The new WATCHMAN FLX device was designed for simplified implantation to fit a wider range of patients, from those with simple to the most complex anatomies. The device allows for implantation flexibility to customize placement with a fully enclosed and rounded frame and by offering physicians the ability to fully recapture and reposition the device during the procedure. Furthermore, the frame of the new device is designed to enhance sealing within the left atrial appendage.

Boston Scientific has begun a limited market release of the WATCHMAN FLX device in Europe and expects to expand commercialization to additional sites in the second half of 2019. The company also plans to begin enrolling European patients in a post-approval registry in the coming months.

In the U.S., the WATCHMAN FLX device is an investigational device and not available for sale.

For more information on the WATCHMAN device, visit www.watchman.com.

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 40 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 business plans 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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[1] "Atrial Fibrillation Fact Sheet." Centers for Disease Control and Prevention. http://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_atrial_fibrillation.htm.

[2] Blackshear JL, Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. Ann Thorac Surg. 1996;61:755-759.

SOURCE Boston Scientific Corporation

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