Boston Scientific

Boston Scientific Receives FDA Approval for LOTUS Edge™ Aortic Valve System

Transcatheter Aortic Valve Replacement Technology for Patients with Severe Aortic Stenosis Designed to Minimize Paravalvular Leakage, Offer Controlled Delivery and Repositionability Post Deployment

MARLBOROUGH, Mass., April 23, 2019 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced it has received U.S. Food and Drug Administration (FDA) approval for the LOTUS *Edge*™ Aortic Valve System. Delivered via a minimally-invasive procedure, this transcatheter aortic valve replacement (TAVR) technology is approved for patients with severe aortic stenosis who are considered at high risk for surgical valve replacement via open heart surgery.

Experience the interactive Multichannel News Release here: https://www.multivu.com/players/English/8297354-boston-scientific-lotus-edge-aortic-valve-system-fda-approval/

"Bringing the much-anticipated LOTUS *Edge* valve system to market allows us to provide patients who aren't good candidates for traditional surgery a safe and effective treatment alternative to restore proper function to their severely narrowed aortic valve," said Kevin Ballinger, executive vice president and global president, Interventional Cardiology, Boston Scientific. "This technology is a fundamental component of our expanding portfolio and demonstrates our continuing commitment to category leadership within the fast-growing Structural Heart treatment landscape."

The LOTUS *Edge* valve system is the only FDA-approved aortic valve that gives physicians the option to reposition and completely recapture the valve once it has been fully deployed. It also features a braided valve frame and an adaptive seal that minimizes paravalvular regurgitation or leaking (PVL) by conforming to the patient's native aortic valve.

"We are thrilled to offer physicians in the U.S. and Europe the clinical benefits of the LOTUS *Edge* valve system for the treatment of their high-risk patients with severe aortic stenosis," said Professor Ian Meredith, AM, executive vice president and global chief medical officer, Boston Scientific. "This system provides physicians a high level of control over the delivery and deployment of the device and offers surgical-like PVL results to help ensure the best patient outcomes."

The FDA approval of the LOTUS *Edge* valve system adds to the Boston Scientific suite of Structural Heart product solutions – including the SENTINEL™ Cerebral Protection System and the WATCHMAN™ Left Atrial Appendage Closure Device – available in the U.S., as well as the ACURATE *neo*™ Aortic Valve System* in Europe.

The company commenced a controlled launch of the valve system in Europe in March and expects to begin a controlled launch in the U.S. in the coming weeks.

For more information about the LOTUS *Edge* valve system, visit bostonscientific.com/LOTUSEdge.

About Aortic Valve Disease
Aortic valve disease results in dysfunction of the aortic valve, one of the four valves that control the flow of blood in and out of the heart. Aortic valve stenosis is the process of thickening and stiffening in the valve, which can result in an abnormal narrowing of the aortic valve opening and reduction in blood flow. Aortic stenosis is the most common valvular heart disease in the world, affecting approximately 7 percent of the population over age 65.[1] From the onset of severe aortic stenosis symptoms, the average survival rate is 50 percent at two years and 20 percent at five years without aortic valve replacement.[2,3]

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.

**The ACURATE neo™ valve system is not available for use or sale in the US.*

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, product launches, 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] Arora S, et al. "Transcatheter Aortic Valve Replacement: Comprehensive Review and Present Status." Tex Heart Inst J. 2017; 44(1):29-38.

[2] Ramaraj R and V.L. Sorrell. "Degenerative Aortic Stenosis." BMJ. 2008; 336(7643):550-555.

[3] Lester, S.J. et al. CHEST 1998; 113:1109-14.

SOURCE Boston Scientific Corporation

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