Boston Scientific

Late-Breaking Data from PROTECTED TAVR Trial Demonstrate Reduced Risk of Disabling Stroke, Low Complication Rate with SENTINEL™ Cerebral Protection System

Results from largest randomized TAVR trial to date presented at TCT 2022

MARLBOROUGH, Mass., Sept. 17, 2022 /PRNewswire/ -- Boston Scientific Corporation (NYSE:BSX) has announced results from the PROTECTED TAVR clinical trial evaluating the SENTINEL™ Cerebral Protection System, which is designed to capture and remove embolic debris stemming from transcatheter aortic valve replacement (TAVR) before it can reach the brain and potentially cause a stroke. Outcomes were presented during a late-breaking clinical science session at the 34th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation, in Boston, and will be published in the *New England Journal of Medicine.*

This randomized trial evaluated periprocedural stroke reduction and neurologic outcomes in patients with aortic stenosis treated with either the SENTINEL device to provide cerebral embolic protection (CEP) during TAVR or TAVR alone. The primary endpoint was not met, as the data demonstrated a non-significant trend towards a lower rate of stroke in patients treated with the SENTINEL device, representing a 21% relative risk reduction in all stroke through 72 hours or time of hospital discharge (2.3% with TAVR and CEP vs. 2.9% with TAVR only, P=0.30). Importantly, a secondary analysis demonstrated a statistically significant 60% relative risk reduction in disabling stroke through 72 hours or time of hospital discharge in patients treated with the SENTINEL device (0.5% with TAVR and CEP vs. 1.3% with TAVR only, P=0.02).

"Data from the PROTECTED TAVR trial provide the physician community with evidence that the device plays an important role in reducing disabling strokes across patient types in those undergoing TAVR," said Dr. Samir Kapadia, chairman of the Robert and Suzanne Tomsich Department of Cardiovascular Medicine, Sydell and Arnold Miller Family Heart, Vascular & Thoracic Institute, Cleveland Clinic. "We also found that the rate of vascular complications in this trial was very low, whether or not the device was used, highlighting the safety of this technology in TAVR procedures."

While outcomes with TAVR for the treatment of aortic stenosis have been shown to be comparable to surgery, stroke remains an important and feared complication of the procedure. Representing the largest randomized TAVR trial to date, the study enrolled 3,000 patients spanning more than 50 global sites and all surgical risk levels, with all patients receiving a neurological exam before and after the procedure. Subgroup analyses demonstrated that the reduction in disabling stroke with the SENTINEL device was consistent across patient subgroups, including age, gender, operative risk, valve type and history of cardiovascular disease.

"Considering strokes are unpredictable, can occur regardless of an individual's clinical background and often take a great toll on a patient's quality-of-life and financial stability, we believe the data appear to demonstrate a consistent effect from CEP technology across all patient populations in the trial – supporting the use of the SENTINEL device as an effective therapy to reduce the risk of the most debilitating form of stroke for patients undergoing TAVR," said Dr. Ian Meredith, global chief medical officer, Boston Scientific. "We look forward to additional data on this technology such as from the currently enrolling PROTECT TAVI trial in the United Kingdom, which will similarly evaluate TAVR-related stroke reduction using the SENTINEL device."

Previous clinical trials involving more than 3,500 patients have demonstrated that the SENTINEL device is safe and effective, including capture and removal of cerebral embolic debris in 99% of TAVR cases.1 To date, more than 75,000 patients worldwide have been protected with this technology.

To learn more about the results of the PROTECTED TAVR trial, visitwww.bostonscientific.com/sentinel.

About Boston Scientific
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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, 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

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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] SENTINEL IDE Trial. Data presented at SENTINEL FDA Advisory Panel,February 23, 2017.

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Additional assets available online: Photos (1)

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