Boston Scientific

Late-Breaking Post-Market Study Data Reinforce Clinical Procedural Success and Safety of the ACURATE neo2™ Aortic Valve System

MARLBOROUGH, Mass., Nov. 27, 2022 /PRNewswire/ -- Boston Scientific Corporation (NYSE:BSX) has announced the first results from the ACURATE neo2 Post Market Clinical Follow-up (PMCF) study evaluating the performance of the ACURATE *neo2*™ Aortic Valve System. The findings, which included a high procedural success rate of 98.4% and low rates of mortality and paravalvular leak (PVL), were presented during a late-breaking clinical trial session at PCR London Valves 2022 and published simultaneously in *EuroIntervention*.

In this European study, the primary safety endpoint of all-cause mortality was 0.8% at 30 days. The data also demonstrated that no patients experienced greater than moderate PVL, 1.9% experienced moderate PVL and 18.9% experienced mild PVL. Other notable findings from the study included a low 6.5% rate of new pacemaker implantation 30 days post procedure, with no incidence of disabling stroke or acute kidney injury.

"With this foundational data set, we now have post-market surveillance results that validate the use of the current-generation ACURATE *neo2* valve for the management of patients with severe aortic stenosis," said Dr. Lars Søndergaard, professor of cardiology, DMSc, FESC, Department of Cardiology, Rigshospitalet and study co-principal investigator. "The data suggest that the annular sealing technology minimizes leakage around the valve – providing greater improvement in PVL than observed with the prior-generation ACURATE *neo* valve – all while maintaining single-digit permanent pacemaker rates, which contributes to better long-term patient outcomes."

The single-arm, prospective ACURATE neo2 PMCF study includes 250 patients with severe aortic stenosis from 18 European centers and will evaluate outcomes for five years following the procedure. It also includes a primary imaging endpoint to assess the visually apparent thickening of the prosthetic valve leaflets (HALT), a phenomenon with theoretical potential effects on valve durability or thrombotic complications. The reported HALT rate of 24.5% at 30 days post procedure falls within the range presented in previous TAVR trials with competitive devices.

"These trial data confirm the success of meaningful and differentiated enhancements included in the design of the ACURATE *neo2* valve, from low rates of PVL and first-time pacemaker implantation to excellent hemodynamic performance and high rates of procedural success and safety," said Dr. Ian Meredith, global chief medical officer, Boston Scientific. "We look forward to reviewing longer-term results from this trial and bringing this differentiated TAVR technology to more patients and their physicians."

The ACURATE *neo2* Aortic Valve System received CE Mark in 2020 and is being evaluated in the currently enrolling ACURATE IDE trial in the U.S. and Canada.

To learn more, visit www.bostonscientific.com.eu/acurateneo2.

*In the U.S., the ACURATE *neo2*™ Aortic Valve System is an investigational device and not available for sale.
** Dr. Søndergaard has not been compensated by Boston Scientific Corporation for his work on the ACURATE neo2 PMCF study or his quote within this news release.

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 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.

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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 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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