Boston Scientific Obtains CE Mark for ACURATE Prime™ Aortic Valve System

MARLBOROUGH, Mass., Aug. 27, 2024 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced it has obtained CE mark for the ACURATE Prime™ Aortic Valve System, the newest transcatheter aortic valve replacement (TAVR) technology in the company's structural heart portfolio. The ACURATE Prime valve system is designed with several features to build upon the clinical performance of the ACURATE *neo2*™ platform including an additional valve size, which expands the treatment range to patients with a larger anatomy.

The new ACURATE Prime valve system is indicated to restore function and normal blood flow through a narrowed aortic valve in low, intermediate and high-risk patients with severe aortic stenosis. With a self-expanding, supra-annular design, this device has an enhanced frame that equalizes force across the valve for a stable fit against the native, diseased valve. It also offers physicians a redesigned deployment mechanism for highly accurate valve positioning to help ensure positive patient outcomes.

"The introduction of the ACURATE Prime technology offers physicians a TAVR option designed for streamlined procedural preparation, improved performance in complex cases and simplified delivery for quick and controlled deployment," said Janar Sathananthan, M.D., chief medical officer, Interventional Cardiology Therapies, Boston Scientific. "Further, our clinical experience with the valve to date has shown the ability for precise positioning of the device in a broader population of patients, allowing more clinicians to consider this technology for treatment in challenging or larger heart structures."

The ACURATE Prime valve system will now be available for the treatment of aortic annulus diameters between 20.5 and 29 mm. It will also carry through many of the design features and clinical outcomes demonstrated in global studies with the ACURATE *neo2* platform, including low pacemaker and paravalvular leak rates,[1,2] strong hemodynamic performance,[1] as well as unrestricted coronary access for future procedures.

"We are thrilled to offer physicians a new valve with meaningful improvements for the treatment of an increasing number of patients with aortic valve disease," said Lance Bates, senior vice president and president, Interventional Cardiology Therapies, Boston Scientific. "Built on the ACURATE valve platform, which has been implanted in nearly 80,000 patients globally to date, the ACURATE Prime valve system is engineered to improve long-term cardiac function and provide access for future treatment needs, thereby supporting the lifetime management of these patients."

The company will initiate the launch of the ACURATE Prime valve system in Europe in the coming weeks. For more information on the system, visit https://www.bostonscientific.com/en-EU/medical-specialties/structural-heart/tavi-acurate-prime.html.

*In Europe, the ACURATE *neo2™* Aortic Valve System and the ACURATE Prime™ Aortic Valve System are CE-marked. In the USA, the ACURATE *neo2* Aortic Valve System and the ACURATE Prime Aortic Valve System are investigational devices and are restricted under federal law to investigational use only. Not available for sale.

About Boston Scientific
Boston Scientific transforms lives through innovative medical technologies that improve the health of patients around the world. As a global medical technology leader for more than 45 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 health care. Our portfolio of devices and therapies helps physicians diagnose and treat complex cardiovascular, respiratory, digestive, oncological, neurological and urological diseases and conditions. Learn more at **www.bostonscientific.com** and connect on **LinkedIn** and **X**, formerly Twitter.

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, and new and anticipated product approvals and launches. 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; manufacturing, distribution and supply chain disruptions and cost increases; variations in outcomes of ongoing and future clinical trials and market studies; 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, except as required by law. This cautionary statement is applicable to all forward-looking statements contained in this document.

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[1] Rück A, Kim WK, Abdel-Wahab M, et al. The Early neo2 Registry: Transcatheter Aortic Valve Implantation with ACURATE *neo2* in a European Population. *J Am Heart Assoc*. 2023 Aug;12(15):e029464.
[2] Kim WK, Tamburino C, Möllmann H, et al. Clinical outcomes of the ACURATE neo2 transcatheter heart valve: a prospective, multicenter, observational, post-market surveillance study. *EuroIntervention*. 2023 May 12;19(1):83-92.

SOURCE Boston Scientific Corporation

Additional assets available online: Photos (1) Video (1)

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