Boston Scientific

Boston Scientific Launches ACURATE neo2™ Aortic Valve System in Europe

Next-generation Valve Designed to Reduce Paravalvular Leaking, Improve Procedural Efficiency and Treat More Patients with Expanded Indication over Prior Version

MARLBOROUGH, Mass., Sept. 28, 2020 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced it has initiated a controlled launch of the ACURATE *neo2*™ Aortic Valve System in Europe. This next-generation transcatheter aortic valve implantation (TAVI) technology is a new platform designed with a number of features to improve upon the clinical performance of the original ACURATE *neo* platform. Compared to the previous generation device, the ACURATE *neo2* valve system also has an expanded indication for patients with aortic stenosis – with no specified age or risk level – who are considered appropriate candidates for the therapy by their heart team, including a cardiac surgeon.

Indicated to restore function and normal blood flow through a severely narrowed aortic valve, the ACURATE *neo2* Valve System features a new annular sealing technology designed to conform to irregular, calcified anatomies and further minimize paravalvular regurgitation or leaking (PVL). In addition, the delivery system simplifies access to smaller and complex vessels at the entry site and allows for highly accurate valve positioning while the top-down deployment mechanism further supports stable placement and release to ensure the best patient outcomes.

"We believe having this differentiated valve with the enhanced sealing technology will further drive favorable market experience and growth," said Joe Fitzgerald, president, Interventional Cardiology, Boston Scientific. "Combined with the LOTUS *Edge*™ Aortic Valve System and SENTINEL™ Cerebral Protection System to protect the brain against the risk of TAVI-related stroke, the ACURATE *neo2* valve represents the natural evolution of our complementary dual-valve TAVI toolkit that covers the needs of a wide range of patient cases."

Data from the ACURATE *neo2* CE-Mark Study demonstrated PVL rates for the ACURATE *neo2* Valve System to be lower than previously reported with the current generation ACURATE *neo* valve. At 30 days and 1 year after implantation, respectively, 97% and 97.5% of patients experienced ≤ no/trace or mild PVL, 3.0% and 2.5% of patients experienced moderate PVL and 0% of patients experienced severe PVL.[1,2]

"We are pleased to bring the latest iteration of ACURATE technology to market, offering design improvements that further support procedural performance and optimal outcomes for patients with severe symptomatic aortic stenosis, from those with simple to the most challenging anatomies," said Dr. Ian Meredith, AM, executive vice president and global chief medical officer, Boston Scientific. "The straightforward implant procedure also enables physicians to reduce the length of time patients need to stay in the hospital, without compromising on safety and clinical results."

The ACURATE *neo2* Aortic Valve System received CE Mark in April 2020. In the U.S., the ACURATE *neo2* Valve System is an investigational device being assessed in the ACURATE IDE clinical trial and is not available for sale.

For more information about the ACURATE *neo2* Valve System, please visit www.bostonscientific.eu/acurateneo2.

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.[3] 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.[4,5]

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, 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] Transcatheter aortic valve implantation for severe aortic valve stenosis with the ACURATE neo2 valve system:30-day safety and performance outcomes. Presented by H. Möllmann at PCR London Valves 2018.

[2] Transcatheter aortic valve replacement with the ACURATE neo2 valve system:1-year clinical and hemodynamic outcomes. Presented by H. Möllmann at TVT 2019.

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

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

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

SOURCE Boston Scientific Corporation

Additional assets available online: Photos (1)

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