NewsRelease

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Late-Breaking Registry Data at EuroPCR Congress Demonstrate Reduced Paravalvular Leak and Low Permanent Pacemaker Rates for the ACURATE *neo2*™ Aortic Valve System

MARLBOROUGH, Mass., May 18, 2021 – Data presented at hot line and late-breaking trial sessions today at the EuroPCR 2021 congress demonstrated positive procedural performance, including low rates of paravalvular leakage (PVL) and permanent pacemaker implementation (PPI), of the Boston Scientific (NYSE: BSX) ACURATE *neo2*™ Aortic Valve System within the investigator-initiated Early neo2 Registry[1] and ITAL-neo Registry[2] studies.

"These real-world findings reinforce the effectiveness of the ACURATE *neo2* valve design enhancements – including the 60% larger outer sealing skirt to conform to challenging anatomies – that have minimized PVL and shown excellent clinical outcomes in a broad spectrum of patients when compared to data collected with the previous-generation ACURATE *neo*™ Aortic Valve System," said Dr. Ian Meredith, global chief medical officer, Boston Scientific.

EARLY neo2 Registry Results

The Early neo2 Registry, presented by Dr. Andreas Rück, interventional cardiologist, Karolinska University Hospital Stockholm, is the first large real-world report of clinical experience with the ACURATE *neo2* device. Key findings from this retrospective analysis of 554 patients from 12 European centers included:

- 1.3% post-operative moderate/severe PVL rate which was ~~a~~ lower than the rate ~~than~~ observed in prior studies with the ACURATE *neo* device. The mild and none/trace PVL rates were 33.3% and 65.4%, respectively.[3]
- 6% in-hospital PPI rate, 2.1% in-hospital stroke rate, low 1.3% mortality rate at 30 days and excellent hemodynamics (mean gradient of 9mmHg).

Early neo2 Registry data were further evaluated in a separate quantitative assessment of angiographic aortic regurgitation in ~228 patients treated with either the ACURATE *neo*~~™ Aortic Valve System~~ valve system or ACURATE *neo2* valve system, also presented by Dr. Rück at EuroPCR as a poster.[4] These results demonstrated that the ACURATE *neo2* device was associated with significantly less aortic regurgitation when compared with the prior-generation ACURATE *neo* device, as evidenced by a:

- 5.5% absolute reduction ($p<0.001$) in the percentage of blood that regurgitates back through the aortic valve (mean aortic regurgitation fraction) and
- 12.2% absolute reduction in the rate of angiographically assessed moderate/severe aortic regurgitation.

ITAL-neo Results

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- 56% relative reduction ($p<0.001$) in the percentage of blood that regurgitates back through the aortic valve (mean aortic regurgitation fraction) and
- 88% relative reduction ($p<0.001$, down to 1.7% with the ACURATE *neo2* device) in the rate of moderate/severe aortic regurgitation as measured by quantitative aortogram.

The retrospective ITAL-neo Registry, which was presented by Dr. Andrea Buono, interventional cardiologist, Fondazione Poliambulanza Istituto ~~Ospedaliero~~Ospedaliero in Brescia, Italy, included 95 TAVI patients from nine Italian centers and evaluated in-hospital device success and in-hospital patient outcomes with the ACURATE *neo2* device. Findings included:

- 3.1% pre-discharge moderate/severe PVL rate. This rate, in addition to the mild and none/trace PVL rates (56.9% and 40%) was lower than previously reported rates in studies of the ACURATE *neo* device.[5,6]
- 97.9% device success rate, 1.1% in-hospital stroke rate, 11.2% in-hospital new PPI rate and excellent hemodynamics (pre-discharge mean gradient of 8.2 mmHg).[1]

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About the ACURATE *neo2* Valve System

The ACURATE *neo2* Valve System received CE Mark in 2020 and is indicated for patients with aortic stenosis – with no specified age or risk level – who are considered appropriate candidates for transcatheter aortic valve implantation by their heart team, including a cardiac surgeon.

Boston Scientific is currently enrolling patients in the ACURATE IDE, the pivotal U.S. trial evaluating the safety of the ACURATE *neo2* Aortic Valve System. In April, the company received FDA approval to modify the trial design to now study patients with severe, symptomatic aortic stenosis who are at low risk of open-heart surgery, in addition to those at intermediate, high and extreme risk.

*In the U.S., the ACURATE *neo2*™ Aortic Valve System is an investigational device and not available for sale.

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.

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. 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] Rück A. Results from the Early neo2 registry Acurate neo2 TAVI valve. Euro PCR 2021 conference. 2021.
[2] Buono A. Short-term outcomes of a novel self-expanding device: ITAL-neo Registry. Euro PCR 2021 conference. 2021.
[3] Transcatheter Aortic Valve Replacement With the ACURATE neo2 Valve System: 1 Year Clinical and Hemodynamic Outcomes. Presented by H. Möllmann at TVT Chicago 2019.
[4] Ruck A. Quantitative Angiographic Assessment of Aortic Regurgitation Following the ACURATE neo2 Versus ACURATE neo –Valve implantation. Euro PCR 2021 conference. 2021.
[5] Lanz J., et al. Lancet. 2019;394(10209):1619-28.
[6] Tamburino C., et al. Circulation 2020;142:2431–2442.