Boston Scientific

Boston Scientific Eluvia™ Drug-Eluting Vascular Stent System Exhibits Superiority Compared to Bare Metal Stents

Late-breaking data demonstrate superior rates of primary patency and statistically significant sustained clinical improvement

LAS VEGAS and MARLBOROUGH, Mass., Oct. 6, 2021 /PRNewswire/ -- Today, Boston Scientific Corporation (NYSE: BSX) announced positive data for the Eluvia™ Drug-Eluting Vascular Stent System (Eluvia stent) during a late-breaking clinical trial presentation at the Vascular InterVentional Advances (VIVA) meeting in Las Vegas. Data presented included one-year results from the EMINENT trial, which demonstrated superiority of the Eluvia stent compared to self-expanding bare metal stents (BMS) for the treatment of patients with peripheral artery disease (PAD) and superficial femoral artery (SFA) or popliteal artery (PPA) lesions up to 210 mm in length. The study enrolled 775 patients, making it the largest randomized trial of a drug-eluting stent for the treatment of PAD to date.

In the trial, the Eluvia stent exhibited superiority with a primary patency rate of 85.4% versus 76.3% with BMS (p=0.0087)[1]. The analysis also confirmed a significantly greater rate of sustained clinical improvement without reintervention, 83.0% for patients treated with the Eluvia stent compared to 76.6% for those treated with BMS (p=0.0450). Further, there was no significant difference in major adverse events or all-cause mortality rates between patients treated with the Eluvia stent and those treated with BMS through one year.

"I am honored to have been part of this global study, which adds to the robust body of evidence from the IMPERIAL trial and confirms that the Eluvia stent should be considered the stent of choice for treating SFA and PPA lesions of intermediate length," said Professor Yann Gouëffic, M.D., Department of Vascular and Endovascular Surgery at Paris Saint-Joseph Hospital,France and principal investigator of the EMINENT study.[2] "The superior primary patency rates and greater rates of clinical improvement without reintervention are reassuring for physicians looking to make clinically-based treatment decisions for their patients and reduce the need for repeat procedures."

The Eluvia stent was developed for the treatment of PAD – the narrowing of the arteries of the legs due to plaque buildup – which affects approximately 8.5 million people in the United States and more than 200 million people worldwide.[3,4] Left untreated, PAD restricts blood flow to the legs and feet and patients often experience pain, swelling and a diminished quality of life. The Eluvia stent, which features sustained release of the lowest dose of paclitaxel of any peripheral drug-eluting device, re-opens blocked arteries and restores blood flow while utilizing a drug-polymer combination to prevent tissue regrowth.

"We are committed to meaningful clinical trials designed to evolve clinical practice, and on the heels of the positive RANGER II SFA data presented yesterday, we are pleased that the EMINENT trial establishes the Eluvia stent as the first drug-eluting stent to demonstrate superior primary patency rates compared to bare metal stents in a head-to-head randomized trial," said Michael R. Jaff, D.O., chief medical officer and vice president clinical affairs, technology and innovation, Peripheral Interventions, Boston Scientific. "The breadth of our portfolio, as the only company offering both a drug-coated balloon and a drug-eluting stent for the treatment of patients with PAD, provides physicians with evidence-based and highly-differentiated treatment options."

For more information on the Eluvia stent, visit www.bostonscientific.com/eluviaclinicaltrials.

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 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, clinical trials, 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] Kaplan Meier estimate

[2] Professor Yann Gouëffic is a paid consultant for Boston Scientific Corporation. He has not been compensated for his quote within this press release.

[3] Centers for Disease Control: https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_pad.htm Accessed September 2, 2021.

[4] Shu, J. & Santulli, G. (2018, August). Update on peripheral artery disease: Epidemiology and evidence-based facts. Atherosclerosis Journal, 275(1), 379-381. doi: https://doi.org/10.1016/j.atherosclerosis.2018.05.033.

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