Boston Scientific

# CMS Grants Additional Reimbursement For The Eluvia™ Drug-Eluting Vascular Stent System

MARLBOROUGH, Mass., Sept. 3, 2020 /PRNewswire/ -- Boston Scientific (NYSE: BSX) announced that the U.S. Centers for Medicare and Medicaid Services (CMS) granted a New Technology Add-on Payment (NTAP) for the Eluvia™ Drug-Eluting Vascular Stent System as part of the 2021 Inpatient Prospective Payment System (IPPS). The NTAP designation, awarded to new medical devices determined to substantially improve the diagnosis or treatment of Medicare beneficiaries, will be effective on October 1, 2020 and will provide eligible hospitals with incremental reimbursement for the Eluvia stent system for up to three years. The Medicare criteria for an NTAP designation is based on newness of the device, cost and a substantial clinical improvement.

The Eluvia stent system was developed for the treatment of peripheral artery disease (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.[i],[ii] 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 re-opens the blocked artery and restores blood flow, while also utilizing a drug-polymer combination to offer a sustained, low-dose release of drug to prevent tissue regrowth within the stented artery.

"The CMS determination is a very positive development for patients with PAD and supports what we have confirmed through our clinical trials – the Eluvia stent offers clinically superior outcomes compared to other peripheral drug-coated technology available to clinicians and their patients," said Jeff Mirviss, executive vice president and president, Peripheral Interventions, Boston Scientific. "The decision is particularly important given the level of consideration and evaluation related to the role of paclitaxel in the peripheral vasculature, and we believe this designation reflects the unique attributes of the Eluvia stent, which are clearly differentiated and improve the quality of life for the millions of people suffering from symptoms of PAD."

The NTAP designation will support access to the Eluvia stent for Medicare beneficiaries in the hospital inpatient setting, making it possible for eligible hospitals to receive NTAP payment in addition to the standard Medicare Severity Diagnosis Related Group (MS-DRG) payment.

The FDA approval of the Eluvia stent system in September 2018 was based on findings from the IMPERIAL trial, which exhibited the highest 24-month primary patency reported to date for the treatment of femoropopliteal disease in a U.S. pivotal trial with a drug-coated balloon or drug-eluting stent.[iii] Trial data confirmed a statistically significant lower clinically-driven target lesion revascularization (TLR) rate of 12.7% for patients treated with the Eluvia stent, in contrast to 20.1% observed within the Zilver® PTX® Drug-Eluting Peripheral Stent cohort (p=0.0495), thus reducing the need for repeat procedures at 24 months.[iv]

Additional information on the Eluvia stent system can be found online at www.bostonscientific.com/drugeluting.

**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 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.

CONTACTS:

Karin Dalsin
Media Relations
(763) 494-1914 (office)
Karin.Dalsin@bsci.com

Susie Lisa, CFA
Investor Relations
(508) 683-5565 (office)
BSXInvestorRelations@bsci.com

[i] Centers for Disease Control: https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_pad.htm Accessed July 19, 2019.

[ii] 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.

[iii] Highest-two year primary patency based on 24-month Kaplan-Meier estimates reported for IMPERIAL, IN.PACT SFA, ILLUMENATE, LEVANT II and Primary Randomization for Zilver PTX RCT.

[iv] Gray WA, Two-year Outcomes from the IMPERIAL Randomized Head to Head Study of Eluvia DES and Zilver PTX. LINC, January 2020.

SOURCE Boston Scientific Corporation

---

https://news.bostonscientific.com/2020-09-03-CMS-Grants-Additional-Reimbursement-For-The-Eluvia-TM-Drug-Eluting-Vascular-Stent-System