BOSTON SCIENTIFIC RECEIVES U.S. FDA APPROVAL FOR THE ELUVIA™ DRUG-ELUTING VASCULAR STENT SYSTEM

First peripheral vascular interventional technology approved in the U.S. to offer sustained release of antiproliferative drug to treat patients with peripheral artery disease

MARLBOROUGH, Mass. (September 24, 2018) – Today, Boston Scientific (NYSE: BSX) announced that the U.S. Food and Drug Administration has approved its Premarket Approval (PMA) application to market the Eluvia™ Drug-Eluting Vascular Stent System, specifically developed for the treatment of peripheral artery disease (PAD). The Eluvia stent utilizes a drug-polymer combination to offer sustained release of the drug paclitaxel for a one-year timeframe, designed to prevent tissue regrowth that might otherwise block the stented artery.

Approximately 8.5 million people in the United States are affected by PAD, which occurs when fatty or calcified atherosclerotic material, called plaque, builds up on the walls of the arteries of the legs, restricting blood flow and causing pain, swelling and a diminished quality of life.[1] If blood flow is not restored and maintained, severe cases of PAD can lead to pain, ulcers and even amputation of the affected limb.

“Over the past decade, we’ve seen significant advancements in the treatment of peripheral artery disease, yet clinical and economic outcomes still present an opportunity for innovation and to improve patient care,” said Jeff Mirviss, senior vice president and president, Peripheral Interventions, Boston Scientific. “With the FDA’s approval of the Eluvia stent, we can now bring the transformative power of sustained drug release to clinicians and the millions of patients suffering from this terrible disease.”

The FDA’s approval is based on findings from the IMPERIAL trial, in which the Eluvia stent demonstrated superior results in the first superficial femoral artery head-to-head drug-eluting stent trial. [2] In this trial, patients treated with the Eluvia stent experienced significantly greater 12-month primary patency of 88.5 percent, compared to 79.5 percent in patients treated with Zilver PTX (p=0.0119).[3] In addition, patients treated with the Eluvia stent experienced half the target lesion revascularization rate of Zilver PTX at 12 months, a 4.5 percent TLR rate for Eluvia versus 9.0 percent TLR rate for the Zilver PTX cohort.

“In the IMPERIAL trial, the Eluvia stent demonstrated landmark vessel patency and freedom from target lesion revascularization rates, preventing more than 95 percent of patients from needing a reintervention after one year,” said William Gray, M.D., system chief, Division of Cardiovascular Diseases and president, Lankenau Heart Institute at Main Line Health in Wynnewood, Pennsylvania, and co-principal investigator of the IMPERIAL trial. “The Eluvia stent is a breakthrough therapy that marks a significant step forward in the treatment of peripheral artery disease, and now with its approval and commercial availability, it has the potential to make an immediate impact on the quality and value of care that physicians can provide to their patients.”

The Eluvia stent system is built on the Innova™ Stent System platform, a self-expanding nitinol stent that has been designed for use in the superficial femoral and proximal popliteal arteries, the main arteries that supply blood to the legs. The Eluvia stent system received CE Mark in 2016.

1. Centers for Disease Control: https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_pad.htm Accessed September 14, 2018
2. Superiority determined in Post Hoc Full Cohort Superiority Analysis. 12-Month Primary Patency rate of 86.8 percent in the Eluvia arm vs. 77.5 percent in the Zilver PTX arm (p-value = 0.0144).
3. Kaplan Meier Estimate

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 35 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 clinical outcomes, product launches, 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; the closing and integration of acquisitions; 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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