Boston Scientific

Boston Scientific Receives CE Mark For Eluvia™ Drug-Eluting Vascular Stent and Announces Initiation of New Clinical Trial

First polymer-based, drug-eluting stent designed to treat peripheral lesions above the knee approved in Europe; IMPERIAL trial initiated to seek regulatory approvals in U.S. and Asia

MARLBOROUGH, Mass., Feb. 22, 2016 /PRNewswire/ -- Boston Scientific (NYSE: BSX) today announced that theEluvia™ Drug-Eluting Vascular Stent System has received CE Mark and is commencing commercialization immediately in the European Union and other countries where CE Mark is recognized.

The Eluvia Stent System is designed to restore blood flow in the peripheral arteries above the knee – specifically the superficial femoral artery and proximal popliteal artery. The stent features a unique drug-polymer combination intended to facilitate sustained release of the drug (paclitaxel) that can prevent narrowing (restenosis) of the vessel, often the cause of pain and disability for patients diagnosed with peripheral artery disease.

CE Mark approval was based on data from the MAJESTIC trial, a prospective, multicenter clinical trial that assessed the safety and performance of the Eluvia Stent System and reflected a primary patency rate of more than 96 percent[1]. The MAJESTIC trial results represented the highest 12-month primary patency reported for an interventional treatment of femoropopliteal artery lesions among comparable trials.

"The exceptional 12-month results presented in the MAJESTIC trial, which included a high percentage of patients with complex lesions, demonstrate that this technology is a safe and efficacious solution for patients needing stents for the treatment of peripheral artery disease," said Professor Stefan Müller-Hülsbeck, M.D., PhD, principal investigator at the Vascular Center Diako Flensburg and head of the Department of Diagnostic and Interventional Radiology / Neuroradiology, Academic Hospitals Flensburg, Germany. "The approval is a testament to the strength of the data, and will be welcome news to physicians and patients who have not previously had access to a polymer based, drug-eluting stent, specifically developed for the superficial femoral and proximal popliteal arteries."

Boston Scientific received an Investigational Device Exemption (IDE) to conduct a global, prospective trial called the IMPERIAL trial, which will assess the safety and efficacy of the Eluvia Stent System compared to the Zilver® PTX® Stent manufactured by Cook Medical. Enrollment began in Q4 last year and the study will include approximately 485 patients in 75 sites worldwide.

"The availability of the Eluvia Stent System to European patients, paired with the expansion of our existing clinical program, demonstrates the momentum of our drug-eluting portfolio in combatting peripheral artery disease," said Jeff Mirviss, senior vice president and president, Peripheral Interventions, Boston Scientific. "Our legacy with drug-eluting technology, combined with our commitment to further advance treatment options for peripheral artery disease, enables Boston Scientific to continue bringing ground breaking solutions for patients around the world."

About the Eluvia Stent System
The Eluvia Stent System is the first stent specifically designed for deployment in the superficial femoral artery (SFA) that utilizes the anti-restenotic drug paclitaxel in conjunction with a polymer. This drug and polymer combination is intended to facilitate sustained release of the drug over the period of time when restenosis is most likely to occur, preventing tissue growth that might otherwise block the stented artery. The Eluvia Stent System is built on the Innova™ Stent System platform, consisting of a self-expanding nitinol stent and an advanced, 6F low-profile triaxial delivery system for added support and placement accuracy. The innovative stent architecture features a closed-cell design at each end of the stent for more predictable deployment, and an open-cell design along the stent body for improved flexibility, strength and fracture resistance. **View or download an image of the Eluvia Stent System.**

In the U.S., the Eluvia Stent System is an investigational device and is not available for sale.

About Peripheral Artery Disease
Peripheral artery disease (PAD) occurs when fatty (plaque) or calcified material builds up in the walls of the arteries and makes them narrower, thus restricting blood flow. When this occurs, the muscles in the legs cannot get enough blood and oxygen, especially during exertion such as exercise or walking. The main symptoms of PAD are pain, burning, or general discomfort in muscles of the feet, calves, or thighs. As the disease progresses, plaque accumulation may significantly reduce blood flow through the arteries, resulting in pain (claudication) and increasing disability, with severe cases often leading to amputation of the affected limb. It is estimated that 200 million people are affected by PAD worldwide.

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 our business plans, regulatory approvals, clinical trials, 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:
Timette Nevala
Media Relations
Boston Scientific Corporation
(763) 494-1284 (office)
Timette.Nevala@bsci.com

Susie Lisa, CFA
Investor Relations
Boston Scientific Corporation
(508) 683-5565 (office)
investor_relations@bsci.com

1. Primary patency defined as duplex ultrasound peak systolic velocity ratio≤ 2.5 and absence of TLR or bypass; data reflect actual values (not Kaplan Meier estimates).

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