Boston Scientific

Boston Scientific Eluvia Drug-Eluting Stent Demonstrates Superior Results In IMPERIAL Trial

First head-to-head trial assesses effectiveness of sustained drug release in interventional treatment for patients with blockages in femoropopliteal arteries

SAN DIEGO and MARLBOROUGH, Mass., Sept. 22, 2018 /PRNewswire/ -- Today, Boston Scientific (NYSE: BSX) announced positive 12-month data from the IMPERIAL trial, the first head-to-head drug-eluting stent trial in the superficial femoral artery (SFA). Results were presented during a late-breaking clinical trial session at the 30th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation, in San Diego, and at the annual Cardiovascular and Interventional Radiological Society of Europe (CIRSE) congress in Lisbon, Portugal. The clinical findings will be published in *The Lancet*.

The IMPERIAL trial evaluated the Eluvia™ Drug-Eluting Vascular Stent System versus the Zilver® PTX® Drug-Eluting Peripheral Stent in patients with symptomatic peripheral artery disease (PAD). PAD 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, ulceration and in some cases, the need for amputation of the affected limb. Stents are commonly used to restore and maintain blood flow, reducing symptoms and improving quality of life.

In the IMPERIAL trial, the Eluvia stent, which utilizes a drug-polymer combination to offer sustained release of the drug paclitaxel, exhibited superior rates of primary patency, a measure of the target vessel remaining unobstructed at 12 months, and thus able to provide sufficient blood flow to the lower limbs.[1] Patients in the Eluvia arm of the study also experienced higher rates of freedom from target lesion revascularization (TLR), thus reducing their need for repeat procedures at one year, when compared to those treated with the drug-coated Zilver PTX. Key findings from the IMPERIAL trial include:

- Patients treated with the Eluvia stent had a statistically significant difference in the primary patency rate of 92.1 percent, compared to 81.8 percent in patients treated with the Zilver PTX (p=0.0119);[2*]
- Data demonstrated that the Eluvia stent had half the TLR rate at 4.5 percent, in contrast to 9.0 percent observed within the Zilver PTX cohort;
- Over 95 percent of patients who received the Eluvia stent were free of major adverse events at one year, compared to 91.0 percent of patients who received the Zilver PTX.

"These impressive clinical outcomes suggest that sustained elution of paclitaxel, delivered by the Eluvia stent, better matched the timing of restenosis in the SFA that can occur months later, thereby reducing the need for repeat interventions," said William Gray, M.D., system chief, Division of Cardiovascular Disease at Main Line Health, president, Lankenau Heart Institute in Wynnewood, Pennsylvania, and co-principal investigator of the IMPERIAL trial. "Based on these findings, we believe that the Eluvia stent can be a preferred therapy option when treating patients with arterial blockages in the superficial femoral or proximal popliteal arteries."

The IMPERIAL trial is a global, multi-center, randomized controlled trial that included 465 patients with superficial femoral artery (SFA) and proximal popliteal artery (PPA) lesions up to 140mm in length. It is the first head-to-head trial comparing two different drug-eluting stent systems for the treatment of PAD.

"We are pleased by the superior results exhibited by the Eluvia stent," said Ian Meredith, M.D., executive vice president and global chief medical officer, Boston Scientific. "The results from the IMPERIAL trial add to the growing body of evidence supporting the use of the Eluvia stent as a frontline therapy for patients, even those suffering from the most challenging cases of superficial femoral artery disease."

The Eluvia Stent System received CE Mark in February of 2016. In the U.S., the Eluvia Stent System is an investigational device and is not available for sale.

1. Superiority determined in Post Hoc 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).
2. Kaplan Meier Estimate

**Revised on January 28, 2020, to reflect an updated 12-month primary patency rate of 92.1% for the Eluvia stent and 81.8% for patients treated with Zilver PTX. The original press release cited 88.5% for the Eluvia stent and 79.5% for Zilver PTX.*

About Boston Scientific
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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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