Boston Scientific

Boston Scientific Announces Positive Data for the Ranger™ Drug-Coated Balloon and the Eluvia™ Drug-Eluting Vascular Stent at VIVA19

Late-breaking clinical trial data demonstrate high rates of primary patency and significantly lower rates of clinically-driven target lesion revascularization for peripheral drug-eluting device portfolio

LAS VEGAS and MARLBOROUGH, Mass., Nov. 5, 2019 /PRNewswire/ -- Today, Boston Scientific (NYSE: BSX) announced positive data for two devices within the peripheral drug-eluting product portfolio during separate late-breaking clinical trial presentations at Vascular InterVentional Advances (VIVA) meeting in Las Vegas. Data presented included a 12-month interim analysis from the RANGER II SFA trial of the Ranger™ Drug-Coated Balloon (DCB) as well as 24-month results from the IMPERIAL trial of the Eluvia™ Drug-Eluting Vascular Stent (DES), 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 DCB or DES.[i]

The RANGER II SFA study evaluated the safety and effectiveness of the Ranger DCB, which has a low drug dose density of paclitaxel, versus standard percutaneous transluminal angioplasty (PTA) for the treatment of patients with peripheral artery disease (PAD) in the superficial femoral artery (SFA) and proximal popliteal artery (PPA).

In the trial, the Ranger DCB exhibited a primary patency rate – a measure of the target vessel remaining unobstructed at 12 months – of 89.2% compared to 72.9% percent in patients treated with standard PTA (p=0.0022), by Kaplan Meier estimate. Additional key findings from the trial include:

- Patients treated with the Ranger DCB had a significantly lower target lesion revascularization (TLR) rate of 6%, in contrast to 17.9% observed with standard PTA (p=0.0018), substantially reducing the patient's need for repeat procedures at 12 months;
- No difference in all-cause mortality at 12 months with a 2.3% rate for the patients treated with Ranger DCB vs. 2.5% in patients treated with standard PTA (p>.99);
- Data from the Pharmacokinetics (PK) sub-study showed that 11 of 12 patients with an average lesion length of 154.2mm had unmeasurable paclitaxel levels in venous plasma approximately one hour after DCB deployment and removal.

"These excellent clinical data coupled with the ease of deliverability of the Ranger DCB are reassuring for physicians as we evaluate the most appropriate therapies based on individual patient needs," said Ravish Sachar, MD, University of North Carolina - Rex Hospital Physician-in-Chief for Heart and Vascular services and principal investigator of the RANGER II SFA trial. "The high primary patency rate as well as the significantly lower TLR rate, which reduces the need for repeat procedures, are very encouraging."

Also presented at the meeting was a 24-month analysis of data from the IMPERIAL trial, which evaluated the Eluvia stent versus the Zilver® PTX® Drug-Eluting Peripheral Stent for the treatment of patients with symptomatic PAD that had SFA and PPA lesions up to 140mm in length. The Eluvia stent utilizes a drug-polymer combination and offers controlled delivery and sustained release of the lowest dose of paclitaxel of any peripheral drug-eluting device. In the study, the Eluvia stent exhibited a primary patency rate of 83.0% versus 77.1% with Zilver PTX, by Kaplan Meier estimate, the highest 24-month primary patency reported to date for the treatment of femoropopliteal disease in a U.S. pivotal trial with a DCB or DES.[i] The analysis also confirmed:

- Statistically significant lower clinically-driven TLR rate of 12.7% for patients treated with the Eluvia stent, in contrast to 20.1% observed within the Zilver PTX cohort (p=0.0495), thus reducing the need for repeat procedures at 24 months;
- A low all-cause mortality rate of 7.1% for the Eluvia stent and 8.3% for those treated with the Zilver PTX (p=0.6649), which is within range expected for symptomatic peripheral arterial disease.[ii]

"We are very pleased with the safety and efficacy demonstrated by the Ranger DCB and the Eluvia stent, both of which showed exceptional durability while preventing repeat TLRs in 66% and 40% of treated patients, respectively," said Ian Meredith, M.D., executive vice president and global chief medical officer, Boston Scientific. "The excellent outcomes presented today underscore our commitment to physicians and their patients with PAD. We continue to drive innovation in the drug-eluting vascular space and these results add to the growing body of evidence supporting our therapy options for the treatment of this challenging disease."

The RANGER DCB gained CE Mark in 2014 and the company submitted for U.S. Food and Drug Administration approval of the device earlier this year. The combination of the RANGER DCB as well as the Eluvia stent positions Boston Scientific as the only company to have both a DES and a DCB for the treatment of PAD in their portfolio.

In the U.S., the Ranger DCB is an investigational device and is not available for sale.

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] 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.

[ii] Feringa HH, Bax JJ, Hoeks S, et al. A prognostic risk index for long-term mortality in patients with peripheral arterial disease. Arch Intern Med. 2007;167:2482-2489.

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https://news.bostonscientific.com/2019-11-05-Boston-Scientific-Announces-Positive-Data-for-the-Ranger-TM-Drug-Coated-Balloon-and-the-Eluvia-TM-Drug-Eluting-Vascular-Stent-at-VIVA19