Boston Scientific

Boston Scientific Receives FDA Approval for the Ranger™ Drug-Coated Balloon

Company provides physicians with first portfolio comprised of drug-eluting stent and drug-coated balloon for the treatment of patients with peripheral artery disease

MARLBOROUGH, Mass., Nov. 2, 2020 /PRNewswire/ -- Boston Scientific (NYSE: BSX) announced it has received U.S. Food and Drug Administration (FDA) approval of the Ranger™ Drug-Coated Balloon, developed for the treatment of patients with peripheral artery disease (PAD) in the superficial femoral artery (SFA) and proximal popliteal artery (PPA).

Approximately 200 million people around the world are affected by PAD[1], a common circulatory problem in which plaque builds up and narrows arteries, consequently reducing blood flow to limbs. The Ranger DCB was designed with a low therapeutic drug dose and proprietary coating which efficiently transfers the drug into the tissue, resulting in high primary patency rates and low systemic drug exposure for patients. The low-profile platform of the balloon also assists clinicians in performing streamlined procedures and navigating through challenging anatomy in order to deliver consistent therapy.

"This approval allows us to bring more treatment options with exceptional outcomes and proven safety to U.S. physicians and their patients who are facing this challenging disease," said Jeff Mirviss, president, Peripheral Interventions, Boston Scientific. "Adding the Ranger DCB to our drug-eluting portfolio, which also includes our Eluvia™ Drug-Eluting Vascular Stent System, reinforces our commitment to providing differentiated technology with strong clinical evidence that supports data-driven treatment decisions for millions of patients suffering from PAD worldwide."

The FDA approval is based on results from the RANGER II SFA pivotal trial, which evaluated the safety and effectiveness of the Ranger DCB versus standard percutaneous transluminal angioplasty (PTA) for the treatment of patients with PAD in the SFA and PPA. In the randomized controlled trial, both primary endpoints were met:

- The primary safety endpoint of 12-month freedom from major adverse events (MAE) was 94.1% for those treated with the Ranger DCB versus 83.5% for standard PTA (^{P}non-inferiority <0.0001).[2]
- Additionally, patients who received therapy with the Ranger DCB had a significantly lower target lesion revascularization rate – a component of MAE – of 5.5% in contrast to 16.5% observed with standard PTA (p=0.0011), substantially reducing a patient's need for repeat procedures.[2]
- The primary efficacy endpoint of 12-month binary primary patency – a measure of the target vessel remaining unobstructed – was 82.9% for the Ranger DCB and 66.3% for standard PTA (p=0.0017). Primary patency by Kaplan-Meier estimate was 89.8% for the Ranger DCB and 74.0% for PTA at 12 months (p=0.0005).[2]

"The Ranger DCB eases deliverability for a wide range of lesion complexities via a low profile platform that is compatible with smaller diameter guidewires and has shown consistent results in multiple randomized controlled trials," said Ravish Sachar, M.D., UNC Rex Hospital Physician-in-Chief for Heart and Vascular services and principal investigator of the RANGER II SFA trial. "For physicians seeking to limit systemic drug loss without compromising outcomes, data demonstrate the Ranger DCB is a safe and effective treatment option."

The Ranger DCB also demonstrated nearly 90% primary patency in the investigator-sponsored COMPARE trial[3] – the first head-to-head prospective, randomized controlled trial to compare two different DCBs. In the

trial, the Ranger DCB demonstrated a similar primary patency rate of 88.4% to that of the 89.4% observed with IN.PACT™ Admiral™ Drug-Coated Balloon (Medtronic) by Kaplan-Meier estimate (p=0.81), with a significantly lower drug dose density (2 µg/mm2 paclitaxel versus 3.5 µg/mm2 paclitaxel, respectively).[3,4]

Boston Scientific expects to initiate a registry of the Ranger DCB and the Eluvia stent in the coming months to gather additional real-world evidence, which will add to the breadth of clinical data collected on these devices to date. The registry is expected to include five years of patient follow-up with an emphasis on enrolling patient populations who have been historically underrepresented in clinical trials studying treatments for PAD.

The company announced CE Mark for the Ranger DCB in 2014 and plans to immediately launch the device in the U.S.

For more information on the Ranger DCB, visit http://www.bostonscientific.com/ranger.

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, product launches 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.

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[1] Shu J, Santulli G. Update on peripheral artery disease: Epidemiology and evidence-based facts. Atherosclerosis. 2018;275:379-381.

[2] RANGER II SFA Pivotal Trial 12-Month Results presented by Marianne Brodmann, M.D. LINC 2020. 12-Month Primary Endpoints: Binary Primary Patency = 82.9% for Ranger DCB and 66.3% for PTA (p= <0.0017). Freedom from Major Adverse Events = 94.1% for Ranger DCB and 83.5% for PTA (p <0.0001)

[3] COMPARE Clinical Trial 12-Month Results presented by Sabine Steiner, M.D. LINC 2020. 12-Month Primary Endpoints: Binary Primary Patency = 83.0% for Ranger DCB and 81.5% for IN.PACT DCB (p <0.01). Freedom from Major Adverse Events = 91.0% for Ranger DCB and 92.6% for IN.PACT DCB (p<0.01).

[4] Based on total drug dose for 4mmx60mm or averages for full size matrix per the IN.PACT™ Admiral™ Drug-Coated Balloon Instructions for Use, www.medtronic.com and the Ranger™ Drug-Coated Balloon Instructions for Use.

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Additional assets available online: Photos (1)

https://news.bostonscientific.com/2020-11-02-Boston-Scientific-Receives-FDA-Approval-for-the-Ranger-TM-Drug-Coated-Balloon