Boston Scientific Announces Favorable Twelve-Month Data for Ranger™ Paclitaxel-Coated PTA Balloon Catheter

Boston Scientific today announced results from the RANGER SFA trial for the Ranger™ Paclitaxel-Coated PTA Balloon Catheter at the Charing Cross Symposium, in London. Data demonstrated that the drug-coated balloon (DCB) exhibited both a high rate of primary patency and freedom from target lesion revascularization (TLR) at 12 months, reducing the need for re-interventions to re-establish flow in previously blocked blood vessels.

The prospective, randomized, controlled trial, comparing the Ranger DCB to uncoated PTA balloons, included 105 patients with femoropopliteal lesions, at ten centers in Europe. Results demonstrate 86 percent primary patency and 91 percent freedom from TLR; both findings statistically significantly higher than the control arm of patients treated with an uncoated balloon. Patency was assessed by duplex ultrasound at 12 months post-procedure. Eighty-four percent of patients in the Ranger DCB group presented either with no or mild symptoms associated with claudication, or pain while walking. There were no target limb amputations.

“The rates of primary patency and freedom from target lesion revascularization are amongst the highest observed in this type of first-in-man trials at one year,” said Dierk Scheinert, M.D., Chairman Division of Interventional Angiology, University Hospital Leipzig, Germany and principal investigator of the RANGER SFA trial. “As a clinician, it is important to have a treatment option, like the Ranger drug-coated balloon, that exhibits consistent performance and outcomes; for patients, these attributes impact their quality of life such as alleviating pain and discomfort, as well as reducing the probability of repeat procedures.”

To expand upon these findings, Boston Scientific recently received approval to commence enrollment in the RANGER II SFA study, a randomized Investigational Device Exemption trial designed to evaluate the safety and efficacy of the Ranger DCB versus Standard PTA Balloons. Anticipated enrollment will include up to 400 patients in 70 centers in the U.S., Canada, Europe, Japan and New Zealand. Data from the RANGER II SFA trial is expected to support regulatory submissions in the U.S. and Japan.

“As a pioneer in developing innovative devices for combatting peripheral artery disease, Boston Scientific is committed to offering a complete portfolio of drug-eluting therapies designed to revolutionize the field,” said Jeff Mirviss, president, Peripheral Interventions, Boston Scientific. “Between our drug-coated balloon and drug-eluting stent platforms, we will study over 3,500 patients in twenty global trials and we’re looking ahead to extending therapies that provide clinicians with the tools and evidence they need to treat patients with lower-extremity arterial disease and beyond.”

The Ranger drug-coated balloon received CE Mark in June of 2014 and is an Investigational device and not available for sale in the U.S.

About Peripheral Artery Disease
Peripheral artery disease (PAD) is a circulatory disorder that results from a build-up of plaque in one or more of the arteries, most often in the legs. As the disease progresses, plaque accumulation may significantly reduce blood flow through the arteries, resulting in pain and increasing disability, with severe cases often leading to amputation of the affected limb. It is estimated that 12-14 percent of the general population is affected by PAD[1].

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.eu 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 the closing of the acquisition, the financial and business impact of the transaction, 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; 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.

1. Shammas NW (2007). "Epidemiology, classification, and modifiable risk factors of peripheral arterial disease." Vasc Health Risk Manag 3 (2): 229–34. doi:10.2147/vhrm.2007.3.2.229. PMC 1994028. PMID 17580733

---

https://news.bostonscientific.eu/2017-04-25-Boston-Scientific-Announces-Favorable-Twelve-Month-Data-for-Ranger-TM-Paclitaxel-Coated-PTA-Balloon-Catheter