Boston Scientific

Boston Scientific Reports Favorable Clinical Trial Results Assessing The OffRoad™ Re-Entry Catheter System

Re-ROUTE Trial Data Presented At VIVA 2013 Late-Breaking Session

NATICK, Mass., Oct. 8, 2013 /PRNewswire/ -- The Boston Scientific (NYSE: BSX) OffRoad™ Re-Entry Catheter System demonstrated excellent performance in facilitating the treatment of complete blockages in the major arteries that supply blood to the legs. These blockages, called chronic total occlusions (CTOs), are often associated with peripheral artery disease (PAD). The data from the Re-ROUTE clinical trial were reported today in a late-breaking clinical trial session at the Vascular Interventional Advances Conference (VIVA) in Las Vegas.

In the Re-ROUTE trial, investigators were successful in navigating around challenging CTOs in the enrolled trial patients 84.8 percent of the time using the OffRoad device, exceeding the pre-specified trial goals.

"CTOs in the legs can lead to pain due to lack of blood flow. They also are an indicator of increased risk for major cardiovascular events and can lead to limb amputation and an overall diminished quality of life," said Dr. Andrej Schmidt, Parkhospital Leipzig, Center for Vascular Medicine, Leipzig, Germany, and principal investigator in the Re-ROUTE trial. "In my experience I found the OffRoad System to be a very effective tool for navigating around these challenging blockages, enabling me to treat more patients with peripheral artery disease."

The Re-ROUTE trial is a prospective, single-arm, non-randomized, multicenter (Europe and Canada), post-market study. Results were presented at VIVA 2013 by Dr. Koen Keirse, Regional Hospital Heilig Hart Tienen, Tienen,Belgium. Results included:

- Investigators achieved an 84.8 percent (78/92) technical success rate using the OffRoad System to cross CTOs in the femoropopliteal arteries.
- At 30 days post procedure, 75 percent of patients experienced an improvement of at least one category in the Rutherford classification, a six-stage scale commonly used to assess the severity of symptoms associated with PAD.
- A 3.3 percent device-related major adverse event rate was seen at 30 days, which is below the pre-specified trial goals.

The OffRoad Re-Entry Catheter System includes a balloon catheter with a micro-catheter lancet and is intended to help physicians navigate around complete arterial blockages that might otherwise prevent minimally invasive treatment. The system is designed to pass around the blockage by traveling within the tissue of the vessel wall (subintimal space). Once the catheter has passed the blockage, it re-enters the vessel lumen. A unique conical-shaped positioning balloon is used to expand the subintimal space and direct the micro-catheter lancet to re-enter the lumen. This allows the physician to position a guidewire across the occlusion and treat the blockage using traditional endovascular techniques such as angioplasty and stenting.

"We look forward to adding the OffRoad Re-Entry Catheter System to our industry-leading portfolio of peripheral CTO solutions," said Jeff Mirviss, president, Peripheral Interventions, Boston Scientific. "Peripheral artery disease can be debilitating, and Boston Scientific is committed to working with physicians and hospital systems to bring forward innovative technologies and science that lead to better outcomes for patients worldwide."

The OffRoad Re-Entry Catheter System has received CE Mark approval and is pending U.S. FDA 510(k) clearance. It is currently not available for sale in the U.S. and data from the Re-ROUTE trial supports U.S. regulatory submissions.

To view an image of the OffRoad Re-Entry Catheter System clickhere.

About Peripheral Artery Disease

Peripheral artery disease 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].

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

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 30 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.

About VIVA Physicians

VIVA Physicians is a not-for-profit organization dedicated to advancing the field of vascular medicine and intervention through education and research. VIVA's mission is demonstrated through activities such as supporting a multidisciplinary fellowship, collaborating with international vascular symposia, interacting with policy makers, and supporting and contributing to philanthropy. Since 2003, VIVA Physicians has sponsored an annual symposium in Las Vegas, Nevada where recognized experts from around the world come to share the latest research, learn about innovative technologies and therapies for vascular disease, and discuss the latest efforts to improve vascular patient care. To learn more about VIVA Physicians visit http://www.vivapvd.com. You can also connect with VIVA Physicians onFacebook, Twitter and LinkedIn.

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 clinical trials, product performance, regulatory approvals and competitive offerings. 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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