Boston Scientific

CryoPlasty® Therapy With Boston Scientific PolarCath™ Dilatation System Reduces Restenosis Rates by Nearly 50 Percent in Peripheral Stenting Procedures

NATICK, Mass. and SAN FRANCISCO, Nov. 11, 2011 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) welcomed positive outcomes from the COBRA clinical trial, which evaluated post-dilation of nitinol stents using CryoPlasty® Therapy with the PolarCath™ Peripheral Dilatation System compared to stenting with conventional balloon angioplasty in patients with diabetes presenting with blockages of the superficial femoral artery (SFA). The trial was funded through an unrestricted grant from Boston Scientific.

Results from the prospective, randomized, multi-center trial demonstrated a significant 47 percent relative reduction in binary restenosis rates for patients treated with nitinol self-expanding stents using post-dilation with the PolarCath System. The analysis was presented today during a late-breaking clinical trial session by Principal Investigator Subhash Banerjee, M.D., Chief, Division of Cardiology at VA North Texas Health Care and Associate Professor of Medicine at the University of Texas Southwestern Medical School in Dallas, at the Cardiovascular Research Foundation's annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in San Francisco.

The COBRA trial enrolled 76 patients with 90 SFA lesions who were randomized to CryoPlasty Therapy or conventional balloon angioplasty (CBA) for post-dilation of nitinol stents used to treat SFA blockages. Inclusion criteria included diabetes, severe claudication and SFA lesions requiring stents >5 mm in diameter and >60 mm in length. The primary endpoint is the rate of binary in-segment restenosis determined by duplex ultrasonography.

Follow-up data have been completed on 41 lesions in the CryoPlasty group and 43 lesions in the CBA group. Results at 12 months showed that binary restenosis was significantly lower in the CryoPlasty group (29.3 percent versus 55.8 percent, p=0.01). The secondary endpoint of change in the ankle-brachial index (ABI) from baseline to 12 months showed significant improvement in the CryoPlasty group (0.59$\pm$0.21 to 0.77$\pm$0.30, p=0.004) compared to the CBA group (0.62$\pm$0.19 to 0.65$\pm$0.26, p=0.66). ABI is the ratio of blood pressure in the lower legs to blood pressure in the arms, which can indicate the presence of blocked peripheral arteries (a higher number indicates less peripheral blockage). Procedural success was achieved in 100 percent of procedures in the CryoPlasty group.

"High restenosis rates remain a major limitation for peripheral stenting in treating patients with peripheral artery disease, particularly in patients with diabetes mellitus," said Dr. Banerjee. "Reducing revascularization rates is critical to improving outcomes, and these trial results show that CryoPlasty Therapy can significantly reduce binary restenosis at least to 12 months in the studied patient population."

CryoPlasty Therapy using the PolarCath Peripheral Dilatation System is a novel form of balloon angioplasty designed to treat atherosclerotic lesions in the peripheral arteries. This technology uses nitrous oxide in place of standard saline to fill an angioplasty balloon within a blocked artery, cooling the balloon's surface to -10 degrees Celsius. As the balloon is inflated, its surface cools and dilates the vascular lesion, potentially helping prevent artery re-blockage.

"CryoPlasty has become a useful treatment option for physicians whose patients are suffering from peripheral artery disease," said Jeff Mirviss, President of Boston Scientific's Peripheral Interventions business. "The COBRA trial results validate the use of CryoPlasty Therapy for post-dilation of peripheral stents to modulate vessel response and potentially lower restenosis rates. Boston Scientific is committed to delivering innovative solutions and is pleased to be the only company to offer the CryoPlasty treatment option as part of our expanding peripheral portfolio."

The PolarCath Peripheral Dilatation System is approved in the U.S. for treating blockages in the peripheral vasculature and for post-dilation of self-expanding peripheral vascular stents.

About Peripheral Artery Disease

Peripheral artery disease (PAD), which affects approximately 10 million people in the U.S., results from plaque build-up in one or more leg arteries. As the disease progresses, plaque accumulation may significantly reduce blood flow, resulting in pain and increasing disability. In severe cases, amputation may be necessary as the only treatment option. Although angioplasty, bypass graft surgery and thrombolytic (anti-clotting) therapy have traditionally been used to treat this condition, leg arteries can become blocked again nearly 50 percent of the time within three years after treatment.

About Boston Scientific

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: www.bostonscientific.com.

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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 our business plans, CryoPlasty Therapy with our PolarCath Peripheral Dilation System, clinical trials, product performance and effects 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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