Boston Scientific

Boston Scientific Launches Innovative Crossing Device to Treat Complete Blockages in Peripheral Arteries

NATICK, Mass., Feb. 8, 2012 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announces the U.S. launch of the TruePath™ CTO Device, designed to facilitate the crossing of chronic total occlusions (CTOs, or complete blockages) within the peripheral vasculature. The Company will begin marketing the product immediately in the U.S. and expects to launch the product in Europe and other international markets in the first half of 2012.

CTOs, which represent complete artery blockages, are extremely difficult to treat with standard endovascular devices such as guidewires and other catheter-based technologies. CTO devices permit endovascular treatment in cases that otherwise might require a patient to undergo bypass surgery or risk lower extremity amputation.

"CTOs are very challenging, requiring additional time, resources and patient exposure to imaging contrast and radiation," said J. A. Mustapha, M.D., Director of Endovascular Intervention at Metro Health Hospital in Wyoming, MI. "The TruePath device is an exciting new technology that allows me to effectively penetrate these difficult blockages with greater speed and ease, allowing access to untreated lesions and helping to improve overall patient outcomes."

The TruePath CTO Device features a rotating diamond-coated tip designed to break through occluded peripheral arteries and facilitate the placement of conventional guidewires for treatment of peripheral lesions. The ultra-low 0.018" profile is roughly half the size of competitive devices and is engineered for optimal crossing. Once positioned, the distal tip rotates at 13,000 rpm to facilitate drilling through calcified lesions and other fibrous blockages. The TruePath device requires no capital equipment and is available with an optional extension wire to facilitate catheter exchange and increase the working length beyond 300 cm.

"The TruePath device is another example of innovation in our priority growth area targeting peripheral vascular disease, where a significant number of patients remain undiagnosed or untreated," said Jeff Mirviss, President of the Boston Scientific Peripheral Interventions Division. "This innovative crossing device further expands our growing peripheral interventions portfolio and offers physicians an option to treat patients with challenging lesions in the lower extremities who may have otherwise faced amputation. Addressing this growing health problem through the use of less-invasive devices could greatly improve patient care and ultimately save limbs."

The ReOpen clinical study evaluated the TruePath CTO Device in 85 patients with peripheral artery lesions. Study results demonstrated the device is safe and effective in facilitating the crossing of intraluminal CTOs following resistance or prior failed attempts with a conventional guidewire. In the study, technical success (defined as facilitation of CTO crossing) was achieved in 80.0 percent of patients, while improved post-procedure blood flow was demonstrated in 82.4 percent of patients. Safety was demonstrated with a 98.8 percent freedom from clinical perforation at the time of procedure.

An estimated 17.6 million Americans and more than 30 million people worldwide suffer from peripheral vascular disease[1], which is characterized by blockages in vessels of the lower limbs and associated with high rates of morbidity and mortality. CTOs are estimated to be present in approximately 40 percent of patients treated for symptomatic peripheral artery disease[2].

Boston Scientific acquired the TruePath technology through its acquisition of ReVascular Therapeutics, Inc. in February 2011. The TruePath CTO Device has received 510(k) clearance from the U.S. Food and Drug Administration and carries CE Mark approval.

For more information on the TruePath CTO Device, visit Boston Scientific's Peripheral Interventions website at: www.bostonscientific.com/peripheral-interventions.

About Boston Scientific

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

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, new product launches and launch cadence, regulatory approvals, clinical trials, product performance, clinical outcomes

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.

[1] SAGE Group, 2010; *Peripheral Vascular Disease*, Drs. Alvaro Alonso, David D. McManus and Daniel Z. Fischer.
[2] A. Boguszewski, et al, *Endovascular Today*, May 2010, 33-8.

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