Boston Scientific

MELODIE Clinical Trial Reports Excellent Safety and Efficacy Results for Express™ Vascular LD Stent in the Treatment of Blocked Iliac Arteries

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NATICK, Mass., and PARIS
(NYSE:BSX)

NATICK, Mass., and PARIS, May 16 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced 12-month data from its MELODIE clinical trial. The trial demonstrates the safety and efficacy of the Express™ Vascular LD Peripheral Pre-Mounted Balloon Expandable Stent in the treatment of narrowed or blocked iliac arteries. The trial was designed to prove the non-inferiority of the Express Vascular LD stent in comparison to the PALMAZ® Balloon Expandable Stent in the treatment of blocked iliac arteries. The Company made the announcement at the annual Paris Course on Revascularization (EuroPCR).

"The Express Vascular LD stent demonstrated excellent results at one year with a high clinical success rate," said Luc Stockx, M.D., Department of Medical Imaging, Genk, Belgium and the trial's Principal Investigator. "In meeting its endpoint, the Express Vascular LD stent was equal to the PALMAZ stent in mean percent of luminal diameter, which is a critical measure of sustained patency. This was further supported by persistent improvements in ankle brachial index and Fontaine classification."

MELODIE is a prospective, open-label, single-arm study of 150 patients (with 163 lesions) at nine European sites and one Canadian site designed to assess the Express Vascular LD Peripheral Pre-Mounted Stent in the treatment of stenosed or occlusive atherosclerotic disease (de novo or restenotic) of the iliac arteries. More than 89 percent of the patients were available for the study's one-year evaluation.

The Express Vascular LD stent met its primary endpoint as demonstrated by a six-month mean percent loss of lumen diameter of 16.2 percent with an upper confidence interval of 19.1 percent, which confirmed non-inferiority to the comparison stent. The Express Vascular LD stent also demonstrated an excellent safety profile with no device- or procedure-related deaths and no episodes of distal embolization.

"We are extremely pleased with the results of MELODIE, which demonstrated excellent safety and efficacy results in what is one of the most prevalent forms of peripheral artery disease today," said John Pedersen, President of the Peripheral Interventions business at Boston Scientific.

Peripheral artery disease (PAD) is a condition similar to coronary artery disease and carotid artery disease. In PAD, fatty deposits build up in the inner linings of the artery walls. These blockages restrict blood circulation, mainly in arteries leading to the kidneys, stomach, arms, legs and feet. Risk factors for peripheral artery disease (PAD) include smoking, diabetes, high cholesterol, high blood pressure and family history of heart or vascular disease. Peripheral artery disease affects eight million Americans and is associated with significant morbidity and mortality.

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: http://www.bostonscientific.com/.

This press release contains forward-looking statements. The Company wishes to caution the reader of this press release that actual results may differ from those discussed in the forward-looking statements and may be adversely affected by, among other things, risks associated with clinical trials, the regulatory approval process, reimbursement policies, commercialization of new technologies, litigation, the Company's overall business strategy and other factors described in the Company's filings with the Securities and Exchange Commission.

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