Boston Scientific

CryoPlasty® Provides Alternative to Amputation For Patients With Blocked Arteries Below The Knee

NATICK, Mass. and NEW ORLEANS, March 26 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced excellent one-year results from its Below-The-Knee (BTK) CHILL study, which evaluated the performance of the PolarCath™ Peripheral Dilatation System for the dilatation of stenotic lesions in infrapopliteal arteries (arteries below the knee) when treating the whole leg. Results were presented by principal investigator Tony Das, M.D., Director of Peripheral Interventions at Presbyterian Heart Institute of Dallas at the annual American College of Cardiology Scientific Session in New Orleans.

Critical limb ischemia (CLI) is a result of peripheral vascular disease (PVD), a circulatory disorder that affects approximately 10 million Americans. PVD results from a build-up of plaque in one or more of the arteries of the legs. As the disease progresses, accumulation of plaque may significantly reduce blood flow through the arteries, resulting in pain and increasing disability. In severe cases, amputation may be necessary and the only treatment option. Angioplasty, bypass graft surgery and thrombolytic (anti- clotting) therapy have traditionally been used to treat this condition, but leg arteries become blocked again nearly 50 percent of the time within three years with these treatment options.

One-year results of the BTK CHILL study, a prospective, multi-center trial with 111 limbs treated in 108 patients at 16 sites in the United States, include an 85 percent freedom from amputation rate and a 97 percent procedural success rate (a decrease in vessel narrowing to less than 50 percent), resulting in improved blood flow. These outcomes are particularly encouraging in light of the severity of disease in these patients. The majority of patients in this study exhibited tissue loss at baseline with nonhealing ulcers or focal tissue loss reported in 66 percent of the limbs and gangrene reported in 37 percent of the limbs (some patients reported both focal tissue loss and gangrene). In total, 69 percent of the treated limbs were categorized as either Rutherford Class 5 or 6 at the time of study enrollment.

"Almost 70 percent of patients with critical limb ischemia undergo amputation as the initial treatment," said Dr. Das. "The 12-month results from the BTK CHILL study support the effectiveness of the PolarCath System, which offers a valuable alternative to amputation or invasive surgical bypass procedures in patients who have this painful, historically difficult-to-treat condition."

CryoPlasty Therapy using the PolarCath Peripheral Dilatation Device is a novel form of balloon angioplasty that cools the inside of blocked arteries in the legs while opening them up. This technology uses nitrous oxide to fill an angioplasty balloon within a blocked artery, cooling the balloon's surface to -10 degrees C. As it is inflated, the cold surface of the balloon cools the vascular lesion, which exerts both mechanical and biological effects that may help prevent re-blockage of the artery. Mechanically, CryoPlasty Therapy may enhance the uniformity of lesion dilatation, reducing injury during the procedure. Cooling may also help to prevent the vessel and lesion from "recoiling" or snapping back to its original form. Biologically, cooling promotes a process called apoptosis, which may reduce excessive thickening of the new layer of smooth muscle cells which contributes to restenosis, or reblockage of the artery. Procedures using the PolarCath Peripheral Dilatation System are typically completed in just a few hours and may relieve pain and symptoms, allowing patients to participate in daily life activities they were not able to do with the debilitating effects of CLI.

"Results from BTK CHILL provide very encouraging news for patients who may otherwise undergo invasive surgical bypass procedures or amputation," said John Pedersen, President of Boston Scientific's Peripheral Interventions business. "The PolarCath Peripheral Dilatation System may relieve CLI pain and symptoms, allowing patients to participate in daily life activities they were not able to do with its debilitating effects."

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. Boston Scientific 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 product development and commercialization, clinical trials, intellectual property, regulatory approvals, competitive offerings, integration of acquired companies, Boston Scientific's overall business strategy, and other factors described in Boston Scientific's filings with the Securities and Exchange Commission.

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