Boston Scientific

Boston Scientific Announces Excellent Results for Patients With Blocked Arteries Below the Knee

CryoPlasty® Therapy may be an alternative to surgery or limb amputation

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NATICK, Mass., Sept. 26 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced excellent six-month results from its Below-The-Knee (BTK) CHILL trial. This study, a prospective, multi-center trial with 111 patients at 16 sites in the United States, evaluated the PolarCath™ Peripheral Dilatation System for restoring blood flow and reducing amputation in patients with critical limb ischemia (severe blockages in the arteries below the knee).

The results included a 93 percent freedom from amputation rate, and a 97 percent procedural success rate (defined as a decrease in percent diameter stenosis to less than fifty percent), resulting in improved blood flow. The data were presented by principal investigator Tony Das, M.D., Director of Peripheral Interventions at Presbyterian Heart Institute of Dallas, at the 2006 Vascular Interventional Advances (VIVA) conference in Las Vegas.

Critical limb ischemia (CLI) is a result of peripheral artery disease (PAD). PAD is a circulatory disorder that affects approximately 10 million people in the United States. It 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 prevent further disability or limb amputation.

"Critical limb ischemia is a debilitating condition that is historically difficult to treat," said Dr. Das. "Because balloon angioplasty has the limitation of restenosis, the potential benefits of the PolarCath Peripheral Dilatation System -- based on these encouraging data results -- suggest that CryoPlasty may be a primary therapy for the treatment of CLI."

CryoPlasty® Therapy using the PolarCath Peripheral Dilatation System is a novel form of balloon angioplasty that cools the inside of occluded arteries in the legs while opening the blockages. This technology uses nitrous oxide to fill an angioplasty balloon within a blocked artery, cooling the balloon's surface to -10 degrees Celsius. 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 reduces 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 Device may relieve a significant portion of pain and symptoms, allowing patients to participate in daily life activities they were not able to do with the debilitating effects of CLI.

"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," said John Pedersen, President of Boston Scientific's Peripheral Interventions business. "The BTK CHILL study provides great news for patients who may otherwise undergo invasive surgical bypass procedures or amputation."

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 litigation, clinical trials, the regulatory approval process, reimbursement policies, commercialization of new technologies, intellectual property, and other factors described in the Company's filings with the Securities and Exchange Commission.

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