Boston Scientific

Boston Scientific Announces Two-Year Results From Study of Patients With Renal Artery Disease

RENAISSANCE trial demonstrates durable results for Company's Express® SD Renal Stent in treating hypertensive patients with severe renal artery stenosis

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NATICK, Mass. and NEW ORLEANS, May 3 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced two-year results from its RENAISSANCE study, which was designed to evaluate the safety and effectiveness of the Company's Express® SD Renal Stent(1) in hypertensive patients with atherosclerotic renal artery stenosis (RAS). Results were presented during a podium discussion at the All That Jazz conference in New Orleans by Michael R. Jaff, D.O., Assistant Professor of Medicine at Harvard Medical School and Medical Director of the Vascular Ultrasound Core Laboratory, Massachusetts General Hospital. All That Jazz, a scientific meeting for Interventional Cardiologists, Radiologists and Vascular Surgeons.

RENAISSANCE is a prospective, single-arm, multi-center study involving 100 patients in 14 sites in the United States. All patients had a single, de novo RAS (>=70 percent). The primary endpoint of the study was restenosis, or the re-narrowing of a previously stented vessel, at nine months. The primary nine-month Duplex ultrasound (DUS) endpoint and one-year follow-up have been previously reported; the two-year clinical and DUS data were reported by Dr. Jaff at All That Jazz. RENAISSANCE is the first study to evaluate DUS as a reliable non-invasive method for surveillance of restenosis with persistent accuracy through two-year follow-up.

A total of 117 atherosclerotic aorto-ostial lesions in 100 subjects were analyzed; 93 percent and 90 percent of patients were available for nine-month and two-year clinical follow-up, respectively. High technical and procedural success rates (99 percent) were achieved with excellent concordance (87 percent) between renal artery DUS and angiography for restenosis. The binary nine-month restenosis rate was 21.3 percent.

Significant improvement in systolic blood pressure compared to baseline was noted at nine months which was maintained through two years (p=0.002). Safety results at two years were reported with an aggregate Major Adverse Event (MAE) rate of 15.9 percent and with no instances of stent thrombosis. The nine-month and two-year target lesion revascularization rates (TLR) were 8.1 percent and 14 percent respectively; no MAE-related deaths, or progression to renal replacement therapy were reported through the two-year follow-up period. Two significant embolic events were reported prior to nine months.

"The two-year RENAISSANCE data are very powerful," said Dr. Jaff. "We finally have prospective multi-center data supporting the durability of renal artery stents. The nine-month data revealed excellent correlation between duplex ultrasonography and contrast arteriography. The two-year data revealed no significant loss of patency between nine months and two years, paralleled by the persistent reduction in blood pressure and avoidance of renal replacement therapy."

"The release of the two-year RENAISSANCE results is an exciting step for the Boston Scientific renal program," said John Pedersen, President of Boston Scientific's Peripheral Interventions business. "The RENAISSANCE results have been submitted to the Food and Drug Administration seeking U.S. approval for indication of the Express SD Renal Stent for use in the renal arteries."

Renal artery disease is the narrowing of the blood supply to the kidneys due to atherosclerosis, or the formation of plaque within the arteries. When the kidneys have a normal blood supply, they filter toxins from the blood and help to keep blood pressure in the normal range. Renal artery disease may lead to high blood pressure or poor kidney function.

Renal artery disease can be treated surgically or less invasively via angioplasty (placement of a balloon at the site of the lesion). The balloon is inserted through a small incision in the groin and fed through the artery on a catheter until it is positioned at the site of the blockage. The balloon is inflated, compressing the plaque against the walls of the artery, and then removed. Re-narrowing of the arteries is common with this treatment method, however, leading to the study of stenting as a treatment option. A stent is an expandable metal mesh tube that remains in the artery after the removal of the balloon that supports the vessel wall to maintain blood flow through the newly opened vessel.

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, Boston Scientific's overall business strategy, and other factors described in Boston Scientific's filings with the Securities and Exchange Commission.

(1) The Express® SD Renal Stent is an Investigational Device in the United States.

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