Boston Scientific Announces FDA Clearance for FilterWire EZ™ Embolic Protection System

(August 23, 2004) -- Boston Scientific Corporation (NYSE: BSX) announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration to market its FilterWire EZ Embolic Protection System to treat saphenous vein graft (SVG) disease. The Company plans to launch the product in the United States immediately. Boston Scientific launched the product in Europe and other international markets in September 2003, where it has experienced strong growth since launch.

The FilterWire EZ System is a low-profile embolic filter mounted on a guide wire and is designed to reduce complications during balloon angioplasty and stenting procedures for the treatment of SVG disease. The filter captures embolic material that becomes dislodged during interventions, which would otherwise travel into the microvasculature where it could cause a heart attack. The FilterWire EX™ System, Boston Scientific's first-generation embolic protection product, was the first filter-based system cleared for SVG treatment in the U.S. and was launched in June 2003.

The FilterWire EZ system is designed to enhance the effectiveness and ease of use of the product. It features a new "suspended loop" design that supports the filter, allowing for complete vessel wall apposition and for placement in both straight and curved vessels. The system is also 6F guide catheter compatible, and has enhanced deliverability with a 3.2F crossing profile.

"The suspended loop design and the improved deliverability of the FilterWire EZ System have proved to be clinically important improvements," said David Cox, M.D., U.S. Principal Investigator for the BLAZE clinical registry. "In the BLAZE registry, the FilterWire EZ System showed improved rates of procedural success and reduced the risk of Major Adverse Cardiac Events (MACE) compared to previously studied embolic protection systems."

The FilterWire EZ System was studied in the BLAZE clinical registry, in which the objective was to establish the safety and efficacy of the FilterWire EZ System during balloon angioplasty or stenting procedures in the treatment of SVGs. The BLAZE multi-center registry studied 90 patients at 16 U.S. and six European sites. The primary safety endpoint of the study was the cumulative incidence of MACE, defined as death, Q-wave or non Q-wave myocardial infarction (MI), emergent coronary artery bypass surgery (CABG), or target vessel revascularization (TVR) at 30 days post-procedure. In the BLAZE registry, the incidence of MACE at 30 days was 6.7 percent, compared to 9.9 percent in the FIRE Trial for the FilterWire EX System.

"We are very pleased to provide clinicians with this next-generation technology for treating the challenging anatomy of SVGs," said Paul LaViolette, Boston Scientific Senior Vice President and Group President, Cardiovascular. "Our improvements to the FilterWire EZ System should make it more user friendly and effective, making it an ideal choice for treating these vessels. We are also continuing to investigate additional vessel size diameters and indications for which this product could be beneficial."

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: 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, commercialization of new technologies, third party intellectual property and other factors described in the Company's filings with the Securities and Exchange Commission.

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