Boston Scientific

Boston Scientific Announces Enrollment of First Patient in FLAME Clinical Trial

(July 8, 2004) -- Boston Scientific Corporation (NYSE: BSX) today announced that enrollment has begun in its clinical trial known as FLAME. This prospective, multi-center, randomized study will involve approximately 500 patients at up to 60 sites in the U.S. and 20 sites internationally, and is designed to evaluate the benefits of filter-based embolic protection during primary percutaneous coronary intervention (PCI) in acute myocardial infarction (AMI).

AMI, or a heart attack, occurs when the blood supply to part of the heart muscle is stopped. Most cases of AMI occur in individuals who have coronary artery disease (CAD), or a build-up of plaque in the coronary arteries, which restricts blood flow. Without blood supply, the heart muscle cells die, and if a large area of the heart is damaged by a heart attack, it can cause sudden death. Frequently, AMI may occur when the plaque ruptures and causes a blood clot or thrombus to form in one of the coronary arteries. Quick treatment for AMI is critical. If blood supply can be rapidly restored to the heart, damage to heart tissue may be prevented or more heart tissue can be saved from permanent damage. PCI, which generally refers to balloon angioplasty or the placement of a stent in an effort to open the blocked vessel, may offer a quick treatment option for these patients.

The FLAME Trial will evaluate the use of two sizes of the Boston Scientific FilterWire EZ™ Embolic Protection System, one covering vessel diameters ranging from 2.25 to 3.5 mm and the other covering vessel diameters ranging from 3.5 to 5.5 mm. Approximately one-half of the patients will be randomized to the FilterWire EZ System with aspiration, while the other half will receive primary PCI without embolic protection. The FilterWire EZ System, along with aspiration, is intended to capture the ruptured plaque or thrombus, preventing it from traveling downstream and potentially blocking one of the coronary arteries.

"Embolization has been shown to complicate approximately 15 percent of primary PCIs and is associated with an adverse outcome," said James B. Hermiller, Jr., M.D., St. Vincent's Hospital, Indianapolis, Indiana and the Principal Investigator for the FLAME Trial. "It is our belief that this study will demonstrate that the use of the FilterWire EZ Embolic Protection System during primary PCI for AMI significantly improves patient outcomes."

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. The filter captures embolic material that becomes dislodged during interventions, which might otherwise travel into the microvasculature. The FilterWire EZ System in the 3.5-5.5 mm vessel diameter size is currently pending 510(k) clearance from the FDA to treat saphenous vein graft (SVG) disease. The FilterWire EX™ System, the Company's first-generation product, was the first filter-based system cleared for SVG treatment in the U.S. and was launched in June 2003.

"The FilterWire System is a proven treatment option for physicians who treat patients with SVG disease," said Paul LaViolette, Boston Scientific Senior Vice President and Group President, Cardiovascular. "We're excited that the FLAME trial will give us the opportunity to explore its effectiveness for another important group of patients."

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.
