## Milestone II Registry Reaffirms Positive Safety Outcomes of TAXUS™ Express<sup>2</sup>™ Stent System

(August 31, 2004) -- Boston Scientific Corporation (NYSE: BSX) today announced six-month clinical findings from the European component of its Milestone II Registry. The Company said it has enrolled nearly 3,700 patients worldwide in the registry, which has been designed to assess physician usage patterns and evaluate outcome data for the TAXUS™ Express<sup>2™</sup> paclitaxel-eluting coronary stent system in "real world" patients. The Milestone II registry has enrolled 1,907 patients in Europe alone, where 118 centers were closely monitored. Analysis of the data was presented at the European Society of Cardiology's (ESC) annual meeting in Munich, where the theme is "Diabetics and the Heart."

The results announced today support the safety findings previously documented in the TAXUS clinical program and provide further evidence that the TAXUS Express<sup>2</sup> stent system is widely utilized by physicians in treating difficult lesions and cases, especially in diabetic patients. The Milestone II database reports nearly one third of its European patient population as diabetic, of which 11.5 percent are insulin dependent. Diabetic patients, especially insulin-dependent patients, are considered to be high risk, prone to aggressive and widespread vascular disease, and more likely to experience restenosis following angioplasty with bare metal stents.

Participating physicians praised the quality of the registry data and monitoring practices. "I am very confident about the validity of this data," said Dr. Kari Niemelä, the registry's principal investigator and Director of the Heart Center at University Hospital, Tampere, Finland. "We have managed an unusually high clinical follow-up rate of 96 percent for all European patients. In addition, the monitoring requirements implemented in this registry resulted in a higher quality of data being collected than is typical of registry studies."

In the overall patient population of European data, Boston Scientific reports a 7.1 percent Cardiac Adverse Event rate (cardiac death, myocardial infarction, need for repeat procedures); a rate of 4.2 percent for repeat procedures and a 0.9 percent reported stent thrombosis rate (acute and late angiographically confirmed thrombotic events). Meanwhile, for the diabetic population overall the Cardiac Adverse Event rate was 8.9 percent and the need for repeat procedures was 5 percent.

"The data is even more encouraging considering that more than half the patients enrolled had highly complex lesions," said Michel Darnaud, President of Boston Scientific Europe. "We are very pleased with the findings as they represent some of the most challenging cases our physicians face today."

## About the Milestone II Registry

The Milestone II registry was designed as a follow-up to the Milestone I registry, which focused on the performance of the Express<sup>2</sup>/sup>™ bare metal stent in "real world" usage. A key endpoint of the Milestone II registry will be to compare stent usage patterns and the outcome data from both registries at the 12-month follow-up time point.

On a global basis, the registry has enrolled 3,689 patients, most of whom are finalizing their six-month follow-up data at this time. The registry is web based and includes 164 centers in 32 countries. Twelve-month follow-up data is expected to be announced next year.

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 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 the regulatory process, litigation, competitive product offerings and other factors described in the Company's filings with the Securities and Exchange Commission.

https://news.bostonscientific.com/news-releases?item=58678