## Data in Complex Patients and Lesions from OLYMPIA Registry Support Safety and Efficacy of TAXUS® Liberte<sup>™</sup> Stent System

PRNewswire-FirstCall NATICK, Mass., and WASHINGTON (NYSE:BSX)

NATICK, Mass., and WASHINGTON, Oct. 25 /<u>PRNewswire-FirstCall</u>/ -- Boston Scientific Corporation (NYSE: BSX) today announced positive results from its global TAXUS OLYMPIA registry, supporting the safety and efficacy of the TAXUS® Liberte<sup>™</sup> coronary stent system in real-world patients. The results were announced at the Cardiovascular Research Foundation's (CRF) eighteenth annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, in Washington, D.C.

The TAXUS OLYMPIA results were presented by Martyn Thomas, M.D., F.R.C.P., King's College Hospital, London, United Kingdom, and included 12-month data from the 529 patients in Phase I of the multi-phased registry and preliminary six-month data from the first 2,066 patients in Phase III. Both Phase I and Phase III patients exhibited a broad range of lesion and procedural complexity, reflecting "real world" usage patterns seen in everyday clinical practices. Population characteristics included a high proportion of diabetics (50 percent in Phase I, 32 percent in Phase III), multi-vessel disease (49 percent in Phase I, 59 percent in Phase III), small vessels (40 percent in Phase I and Phase III), and complex lesions (defined as B2/C, 48 percent in Phase I, 60 percent in Phase III).

"The OLYMPIA data from Phases I and III are extremely positive, especially given the high degree of patient and procedural complexity," said Dr. Thomas, the principal investigator for the OLYMPIA registry. "The results show consistency with other TAXUS clinical trials and registries, and build on the strong performance of the TAXUS coronary stent systems in complex lesions. The TAXUS Liberte stent is proving to offer a significant advance in design and deliverability and is a welcome addition to our available treatment options for coronary artery disease."

OLYMPIA Phase I 12-month findings demonstrated an overall TAXUS Liberte stent-related cardiac event rate of 3.7 percent, including myocardial infarction (1.4 percent), and TAXUS Liberte stent-related re-intervention of the target vessel (1.9 percent). Overall cardiac death was 1.5 percent. Phase III six-month results showed an overall TAXUS Liberte stent-related cardiac event rate of 3.0 percent, including myocardial infarction (0.9 percent), and TAXUS Liberte stent-related re-intervention of the target vessel (1.8 percent). Overall cardiac death was 0.9 percent.

Phase I OLYMPIA data reported one additional stent thrombosis from six months to one year, with an overall stent thrombosis rate of 1.7 percent at 12 months. Phase III results demonstrated a stent thrombosis rate of 0.5 percent out to six months. Stent thrombosis rates for both Phases are consistent with safety data from other DES registries.

Low rates of TAXUS Liberte stent-related cardiac events and TAXUS Liberte stent-related re-interventions were also reported in high-risk patient subsets, including diabetics, multiple stents, long lesions and small vessels, and were consistent with overall rates. These patient subsets are typically considered to be at high risk for baremetal stenting.

"We are pleased to see safety and efficacy sustained out to one year with our initial OLYMPIA patients as well as consistent, positive outcomes with our preliminary Phase III patients," said Paul LaViolette, Chief Operating Officer of Boston Scientific. "These results further reinforce the significant benefits of our next-generation TAXUS Liberte drug-eluting stent in treating coronary artery disease, particularly in complex lesions. We look forward to the results of the other OLYMPIA phases, which will include up to 27,000 patients, and to complementing the proven benefits of the TAXUS Liberte stent with our everolimus-eluting PROMUS<sup>™</sup> stent."

Phase I of the OLYMPIA registry enrolled 529 patients at 16 sites in seven countries and met its primary endpoint of TAXUS Liberte stent-related cardiac events at 30 days post implant. Phase III will enroll up to 15,000 patients at up to 250 sites in 20 European countries. The primary endpoint for Phase III is TAXUS Liberte stentrelated cardiac events at 12 months post implant. The global, prospective OLYMPIA registry plans to enroll patients in multiple phases from more than 500 centers in 60 countries and is designed to analyze real-world clinical outcomes data for Boston Scientific's next-generation TAXUS Liberte paclitaxel-eluting stent system in the treatment of patients with coronary artery disease.

The Company received the CE Mark for the TAXUS Liberte stent in Europe and other international markets in September 2005, and it is currently the market-leading drug-eluting stent outside the United States (the TAXUS

Liberte stent is not available for sale in Japan). The TAXUS Liberte stent is currently pending approval by the U.S. Food and Drug Administration and is not available for sale in the United States. The Company plans to launch the TAXUS Liberte stent in the United States in 2007. The Company received the CE Mark for its everolimus-eluting PROMUS stent in October 2006 and plans to launch the PROMUS stent in Europe in early 2007, making Boston Scientific the only company to offer two distinct drug-eluting stent platforms. The PROMUS stent, a private-label XIENCE<sup>™</sup> V Everolimus Eluting Coronary Stent System, is manufactured by Abbott and distributed by Boston Scientific. The PROMUS stent is not available for sale in the United States.

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: <u>http://www.bostonscientific.com/</u>.

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 new 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.

CONTACT: Milan Kofol 508-650-8569 (Office) 617-834-8595 (Mobile) Investor Relations Boston Scientific Corporation

> Paul Donovan 508-650-8541 (Office) 508-667-5165 (Mobile) Media Relations Boston Scientific Corporation

SOURCE: Boston Scientific Corporation

CONTACT: Milan Kofol, Investor Relations, +1-508-650-8569 (Office) or +1-617-834-8595 (Mobile), or Paul Donovan, Media Relations, +1-508-650-8541 (Office) or +1-508-667-5165 (Mobile), both of Boston Scientific Corporation

Web site: <u>http://www.bostonscientific.com/</u>

https://news.bostonscientific.com/news-releases?item=58903