Boston Scientific

SPIRIT IV Results Reaffirm Strong Performance of Boston Scientific PROMUS® and TAXUS® Express® Stents

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NATICK, Mass. and SAN FRANCISCO, Sept. 23 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today welcomed one-year data from the SPIRIT IV clinical trial comparing the XIENCE V(®) (PROMUS(®)) Everolimus-Eluting Coronary Stent System to the TAXUS(®) Express2™ Paclitaxel-Eluting Coronary Stent System. The results support the benefits of paclitaxel-eluting stents in diabetic patients. The trial enrolled 3,690 patients, including 1,140 diabetics, the largest diabetic subset ever studied in a drug-eluting stent clinical trial.

The Company also announced that on October 1 it will begin its previously planned, phased discontinuation of the TAXUS Express Stent used in the SPIRIT IV trial. The TAXUS Express Stent has been replaced by the thinner-strut TAXUS(®) Liberte(®) Stent worldwide. The TAXUS Liberte Stent was approved in Europe in 2005, in the U.S. in 2008 and in Japan in 2009.

The SPIRIT IV results were presented at the 21(st) annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium by Gregg W. Stone, M.D., Professor of Medicine and the Director of Research and Education at the Center for Interventional Vascular Therapy at the Columbia University Medical Center/New York-Presbyterian Hospital, and Principal Investigator of the trial.

"We welcome the positive SPIRIT IV results reaffirming the safety and efficacy of our two drug-eluting stent platforms," said Donald S. Baim, M.D., Chief Medical and Scientific Officer at Boston Scientific. "The strong outcomes among diabetic patients treated with TAXUS Express were impressive, particularly the rates of target lesion failure (TLF) at one year, which were equivalent for PROMUS and TAXUS Express. These rates were actually lower for TAXUS Express in diabetic patients requiring insulin."

The TLF rates for diabetic patients at one year were 6.4% for the XIENCE V (PROMUS) Stent and 6.9% for the TAXUS Express Stent (p=0.80). For diabetic patients requiring insulin, the TLF rates were 8.0% for the XIENCE V (PROMUS) Stent and 7.0% for the TAXUS Express Stent (p=0.83).

SPIRIT IV is a prospective, single-blinded, multicenter clinical trial in which patients with up to three native coronary artery lesions were randomized 2:1 to the XIENCE V (PROMUS) Stent or the TAXUS Express Stent at 66 U.S. sites. The primary endpoint is the rate of ischemia-driven TLF at one year, which is a composite measure of safety and efficacy consisting of cardiac death, target vessel myocardial infarction, and ischemia-driven target lesion revascularization (TLR).

The results showed the trial met its endpoint of TLF non-inferiority with rates of 4.2% for the XIENCE V (PROMUS) Stent and 6.8% for the TAXUS Express Stent (p<0.0001). Contributing to this result was a significant difference in TLR (2.5% for XIENCE V (PROMUS) versus 4.6% for TAXUS Express, p<0.001), including a large subgroup of patients (n=1,352) with vessels smaller than or equal to 2.75 mm. As announced yesterday, the TAXUS ATLAS Small Vessel Trial reported a statistically significant reduction in the rate of TLR in small vessels treated with the 2.25 mm diameter TAXUS Liberte Atom™ Stent compared to the older 2.25 mm diameter TAXUS Express Atom Stent.

SPIRIT IV safety results demonstrated comparable rates of death (1.0% for XIENCE V (PROMUS) versus 1.3% for TAXUS Express, p=0.61) and a non-significant difference in Myocardial Infarction (1.9% for XIENCE (PROMUS) versus 3.1% for TAXUS Express, p=0.02). The overall major adverse cardiac events (MACE) rate was 4.2% for XIENCE (PROMUS) and 6.9% for TAXUS Express (p=0.0009). Stent thrombosis under the ARC (Academic Research Consortium) definite/probable definition was 0.29% for XIENCE (PROMUS) versus 1.1% for TAXUS Express (p=0.004). This difference is inconsistent with results seen

in the SPIRIT II and III trials where rates of ARC stent thrombosis were comparable at one year and remained similar out to three years.

"We are pleased that our thinner-strut TAXUS Liberte Stent has proved so appealing to clinicians as a replacement for the TAXUS Express Stent," said Hank Kucheman, Senior Vice President and Group President, Cardiovascular for Boston Scientific. "We continue to be the only manufacturer offering both everolimus- and paclitaxel-based drug-eluting stent platforms, and we look forward to introducing our upcoming family of platinum chromium Element™ Stents, which will be offered in everolimus, paclitaxel and bare-metal versions."

The TAXUS stent systems -- both Liberte and Express -- have been evaluated by the industry's most extensive randomized, controlled clinical trial program, with follow-up to five years in some cases. These trial results have been supplemented by data on more than 50,000 patients enrolled in post-approval registries. To date, approximately 4.6 million TAXUS stents have been implanted globally, making them the world's most frequently used drug-eluting stents.

The PROMUS Stent is a private-labeled XIENCE V Everolimus-Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific. SPIRIT IV is sponsored by Abbott. TAXUS, TAXUS Express2, Express, Liberte, PROMUS and Element are trademarks of Boston Scientific Corporation or its affiliates. XIENCE is a trademark of Abbott Laboratories Group of Companies.

The TAXUS Liberte Stent has received an indication for use in diabetic patients in CE-Marked countries. In the United States, the TAXUS Express, TAXUS Liberte and PROMUS Stents are not specifically indicated for use in diabetic 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.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding clinical trials, regulatory approvals, product performance and competitive offerings. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and, future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A- Risk Factors in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A - Risk Factors in Quarterly Reports on Form 10-Q we have filed or will file thereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions, or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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