Boston Scientific

Safety Profile of TAXUS® Liberte™ Stent System Highlighted in World's Largest Stent Registry

NATICK, Mass. and VIENNA, Austria, Sept. 2 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced one-year results from the European and Intercontinental launch phases of its TAXUS OLYMPIA registry. The first 7,124 patient cohort of the nearly 23,000 enrolled provided positive safety data on the TAXUS® Liberate™ coronary stent system in complex, real-world patients, as announced at the European Society of Cardiology Congress in Vienna, Austria.

The one-year results demonstrated a low overall 3.9 percent rate of TAXUS Liberte stent related cardiac events, including cardiac death (1.1 percent), myocardial infarction (0.9 percent), and TAXUS Liberte stent related re-intervention of the target vessel (2.5 percent). The one-year stent thrombosis rate was 0.8 percent, which is consistent with safety data from other DES registries.

In the diabetic subset (2,380 patients), OLYMPIA reported a low 4.4 percent rate of overall TAXUS Liberte stent related cardiac events, including cardiac death (1.9 percent), and myocardial infarction (0.8 percent). TAXUS Liberte stent related re-interventions (2.3 percent) and stent thrombosis (0.7 percent) were both lower for the high-risk diabetic patient group than the rates for the overall population.

"The OLYMPIA registry continues to show impressive results, especially given the high degree of complex patient and lesions from real-world practice," said Martyn Thomas, M.D., F.R.C.P., Director of Invasive Cardiology, Kings College Hospital, London, and one of the coordinating investigators of the registry. "The data show consistency with initial results and with data from other TAXUS clinical trials and registries, offering further evidence that the TAXUS Liberte stent system continues to show positive safety outcomes in real-world use."

"The one-year OLYMPIA data show excellent outcomes with the TAXUS Liberte stent system across a large patient population with a broad range of lesion complexity, including diabetics who have typically demonstrated increased event rates," said Jeff Goodman, President of Boston Scientific International. "Our second-generation stent platform - TAXUS Liberte - offers exceptional deliverability and is the only current drug-eluting stent geometry designed specifically for drug elution. The strong clinical results, excellent performance in diabetics and solid physician preference have allowed TAXUS Liberte to take a clear leadership role in European and Intercontinental markets."

The global, prospective OLYMPIA registry is the world's largest DES registry and plans to enroll up to 26,000 patients from more than 400 centers worldwide. OLYMPIA is designed to analyze real-world clinical outcomes data for Boston Scientific's second-generation TAXUS Liberte paclitaxel-eluting stent system in the treatment of patients with coronary artery disease.

The OLYMPIA European and Intercontinental launch phases consisted of diverse and high-risk patient populations, reflecting complex usage patterns in "real-world" clinical practices. A majority of patients exhibited complex lesions or clinical characteristics, including, multi-vessel disease (57.7 percent), prior myocardial infarction (MI) (37.3 percent), acute MI (17.8 percent), multiple stents (32.9 percent), type B2/C lesions (56.6 percent) and diabetes (33.4 percent). Of the first 7,124 patients enrolled, 92.5 percent (6,593 patients) were available for evaluation at one year.

Patients with a single vessel treated with only one TAXUS Liberte stent were considered simple use patients and comprised 27.6 percent of the total. Complex use patients comprised 72.4 percent of the population (5,157 patients) and included patients with acute MI, small vessels, long lesions, in-stent restenosis, and bifurcations, representing lesions not studied in the TAXUS IV and TAXUS ATLAS pivotal randomized controlled trials. Despite the higher complexity, patients in this group demonstrated an overall TAXUS Liberte stent related cardiac event rate of 4.6 percent and a stent thrombosis rate of 1.0 percent.

CAUTION: The TAXUS Liberte stent is an investigational device and is not 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: http://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, product performance, competitive offerings, procedural volume, overall market size and our market position. 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 IA- 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.

CONTACT: Paul Donovan
508-650-8541 (office)
508-667-5165 (mobile)
Media Relations
Boston Scientific Corporation

Dan Brennan
508-650-8538 (office)
617-459-2703 (mobile)
Investor Relations
Boston Scientific Corporation

SOURCE: Boston Scientific Corporation

CONTACT: Media Relations, Paul Donovan, +1-508-650-8541, or mobile, +1-508-667-5165, or For investors, Dan Brennan, +1-508-650-8538, or mobile, +1-617-459-2703, both of Boston Scientific Corporation

Web site: http://www.bostonscientific.com/

---

https://news.bostonscientific.com/safety-worlds-largest-stent-registry