

Boston Scientific

TAXUS OLYMPIA Registry Shows Excellent Outcomes for High-Risk Patients Treated with Second-Generation TAXUS® Liberte® Stent

PRNewswire-FirstCall

NATICK, Mass. and WASHINGTON
(NYSE:BSX)

NATICK, Mass. and WASHINGTON , Oct. 15 [PRNewswire-FirstCall/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced positive one-year results from the Intercontinental and European launch phases of its global TAXUS OLYMPIA registry, the world's largest prospective, post-approval registry for a single drug-eluting stent (DES). OLYMPIA is designed to analyze real-world clinical outcomes data for Boston Scientific's second-generation TAXUS® Liberte® Paclitaxel-Eluting Coronary Stent System in the treatment of patients with coronary artery disease. Outcomes from the 22,000-patient study focused on high-risk lesion subgroups and patients with serious co-morbid conditions. Results were presented by Waqar H. Ahmed, M.D., at the Cardiovascular Research Foundation's (CRF) annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in Washington, D.C.

The TAXUS OLYMPIA registry employs a consecutive enrollment process and consists of diverse and high-risk patient populations, reflecting real-world patients found in everyday clinical practice. One-year data were collected for a total of 22,345 patients to date in 57 countries with cardiac events validated by independent medical review. A large majority of patients (75%) were considered "expanded use" cases consisting of challenging lesions or complex clinical characteristics. The overall OLYMPIA population included patients with multivessel disease (56.5%), prior PCI (27.9%), multiple stents (32.3%), and medically treated diabetes (27.0%).

One-year data demonstrated excellent outcomes for the TAXUS Liberte Stent in patients with high-risk lesions (small vessels, long lesions, B2/C lesions) and patients with co-morbid conditions (prior stroke, acute MI, chronic renal disease). Results demonstrated a low overall 4.4 percent rate of TAXUS Liberte stent-related composite cardiac events, including cardiac death (1.4%), MI (0.9%), and re-intervention (TVR) (3.1%). The definite stent thrombosis rate was 0.8 percent after one year. The TAXUS Liberte Stent also exhibited a high degree of procedural success at 99.7 percent.

"The OLYMPIA registry continues to show impressive safety and efficacy data for the TAXUS Liberte Stent in the largest, prospective DES patient population ever studied for an individual stent," said Dr. Ahmed, Armed Forces Hospital, Jeddah, Saudi Arabia. "The low occurrence of cardiac events and stent thrombosis is noteworthy, especially given the large percentage of high-risk patients and lesions from real-world practice in this study."

In the medically treated diabetic subset of 5,692 patients, OLYMPIA reported a 5.1 percent rate of overall TAXUS Liberte stent-related cardiac events, including cardiac death (2.3%), MI (1.1%), and re-intervention (TVR) (3.1%). Definite stent thrombosis was 0.8 percent, and remained low even in the insulin-treated diabetic patients at 1.0 percent. The diabetic patient subset is typically considered to be at high risk for adverse events associated with bare-metal stenting.

"The one-year OLYMPIA results reinforce the impressive safety and efficacy data seen in the pivotal trial for the TAXUS Liberte Stent," said Donald S. Baim, M.D., Chief Medical and Scientific Officer of Boston Scientific. "This second-generation platform offers thinner struts for exceptional deliverability and a stent geometry designed for more uniform drug elution."

The TAXUS Liberte Stent has been approved by the U.S. Food and Drug Administration and is available for sale in the United States. The safety and effectiveness of the TAXUS Liberte stent have not been established in patients with multi-vessel disease, in-stent restenosis, AMI, multiple stents, lesions longer than 28mm or arteries with an RVD less than 2.5 mm or greater than 4.0mm.

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 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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