Boston Scientific

Journal of American College of Cardiology Article Reports Fewer Repeat Procedures With Boston Scientific's TAXUS® Liberte® Stent

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Authors identify important differences between drug-eluting stent brands

NATICK, Mass., May 11 /PRNewswire-FirstCall/ -- Boston Scientific Corporation today welcomed the publication of an article in the current edition of the Journal of American College of Cardiology (JACC) reviewing data on more than 19,000 patients from the Swedish national registry who were evaluated for restenosis, or the re-narrowing of arteries after percutaneous coronary intervention (PCI). The article reported that patients who received a TAXUS® Liberte® Paclitaxel-Eluting Stent had numerically lower incidences of repeat procedures to treat restenosis at two years as compared to patients treated with 'olimus-based drug-eluting stents (DES), including Cordis' Cypher® Stent and Medtronic's Endeavor® Stent. In the patients with diabetes, the TAXUS Liberte Stent demonstrated a statistically significant lower restenosis rate compared to the Endeavor Stent, which had more than two times the risk of repeat procedures.

The Swedish Coronary Angiography and Angioplasty Registry holds data on all patients undergoing PCI in Sweden. The objective of this independent study was to evaluate restenosis rates of drug-eluting stents in patients with and without diabetes in a real-world setting. The JACC article reported that both the TAXUS Liberte Stent and Boston Scientific's first-generation DES -- the TAXUS® Express® Stent -- were the only stents in the study showing no increased risk of restenosis for patients with diabetes as compared to those without diabetes. Both the Cypher Stent and Endeavor Stent showed significant increased risk of restenosis in patients with diabetes. In addition, the study showed that the TAXUS Liberte Stent had an approximately 23 percent lower restenosis rate at two years compared to the prior-generation TAXUS Express Stent. The authors concluded that "There seem to be important differences between different brands of DES."(1)

"The results of this study are noteworthy for TAXUS Liberte, which compared favorably in rates of repeat procedures to both 'olimus stents," said Donald S. Baim, M.D., Chief Medical and Scientific Officer of Boston Scientific. "The findings presented in the article are consistent with our own clinical trial observations, including recently published ARRIVE and ATLAS data, and may reflect the different mechanism of action for paclitaxel compared to the 'olimus agents used in the other drug-eluting stents. The newer and thinner-strut TAXUS Liberte Stent performed better than the TAXUS Express Stent in reducing restenosis."

The Swedish registry study included four DES brands: TAXUS Liberte,TAXUS Express, Cypher and Endeavor. In total, the registry included 35,478 DES implants during 22,962 procedures in 19,004 patients, with 1,807 restenoses reported over a mean 29-month follow-up period. For the entire study population, the repeat revascularization rate per stent was 3.5 percent after one year and 4.9 percent after two years. Overall, the adjusted risk of restenosis was 1.23 times higher in patients with diabetes than in patients without diabetes. In patients with diabetes, restenosis was higher in the non-TAXUS Stents. The sirolimus-eluting Cypher Stent and the zotorolimus-eluting Endeavor Stent had higher restenosis rates in patients with diabetes compared with those in patients without diabetes (1.25 times and 1.77 times, respectively).

"The Swedish study shows there are significant distinctions among available DES, as well as differences between first- and second-generation products," said Hank Kucheman, Senior Vice President and Group President, Cardiovascular for Boston Scientific. "Our two-drug strategy has allowed us to maintain our global DES leadership position by offering the next-generation TAXUS Liberte Stent as well as the PROMUS® Everolimus-Eluting Coronary Stent. We look forward to introducing our third-generation Element™ Stent on both drug platforms later this year in CE Mark countries."

TAXUS Stents 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 35,000 patients enrolled in post-approval registries. To date, approximately 11 million Boston Scientific stents have been implanted globally, making them the world's most frequently used stents.

The TAXUS Liberte Paclitaxel-Eluting Coronary Stent System received U.S. Food and Drug Administration approval in October 2008, and received European CE Mark approval for use in patients with diabetes in December 2007. In the United States, the TAXUS Stents are not specifically indicated for use in patients with diabetes.

The PROMUS Stent is a private-labeled XIENCE V® Everolimus-Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific. XIENCE V is a trademark of the Abbott Laboratories group of companies. Cypher is a trademark of Cordis Corporation. Endeavor is a trademark of Medtronic Vascular, Inc.

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.

(1) (J Am Coll Cardiol 2009;53:1660-7)

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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, competitive offerings and product performance. 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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