Boston Scientific

FDA Approves Boston Scientific's TAXUS® Liberte® Long Stent

Longest available drug-eluting stent strengthens Company's broad portfolio

PRNewswire
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(NYSE:BSX)

NATICK, Mass., July 16 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced it has received approval from the U.S. Food and Drug Administration (FDA) to market its TAXUS(®) Liberte(®) Long Paclitaxel-Eluting Coronary Stent System, a next-generation drug-eluting stent (DES) designed for long lesions. At 38 mm, it is the longest available DES, providing doctors an option that can potentially reduce the number of stents used in more complex cases, simplifying procedures and reducing costs. It affords a more efficient treatment option for the estimated 8 to 10 percent(1) of patients with long lesions. The Company plans to launch the product in the U.S. next month. It received CE Mark approval in 2007.

"The TAXUS Liberte Long Stent offers physicians and patients distinct advantages compared to using two overlapping drug-eluting stents," said Mark Turco, M.D., FACC, FSCAI, Director of the Center for Cardiac & Vascular Research at Washington Adventist Hospital, Takoma Park, Maryland. "In the ATLAS Long Lesion Trial, the 38 mm TAXUS Liberte Stent significantly reduced myocardial infarction when compared to the TAXUS(®) Express(®) Stent, making the TAXUS Liberte Long Stent an attractive option for interventional cardiologists faced with long, challenging lesions."

The TAXUS ATLAS Long Lesion Trial reported a significant 79 percent reduction in the rate of nine-month myocardial infarction for the TAXUS Liberte Long Stent as compared to the TAXUS Express Stent control (1.3% vs. 6.3%, p=0.026). At two years, the composite measure of cardiac death or myocardial infarction showed a significant 63 percent reduction for the TAXUS Liberte Long Stent compared to the TAXUS Express Stent (3.5% vs. 9.4%, p=0.0426). The rate of stent thrombosis at two years was zero percent for the TAXUS Liberte Long Stent and 0.8 percent for the TAXUS Express Stent(2).

"Today's announcement is the latest example of the breadth of our market-leading drug-eluting stent portfolio," said Hank Kucheman, Senior Vice President and Group President, Cardiovascular for Boston Scientific. "The TAXUS Liberte Long Stent and our TAXUS Liberte Atom(™) Stent -- approved by the FDA in May for use in small vessels -- are key differentiators. No other company offers a 38 mm length or 2.25 mm diameter DES. Our ongoing leadership is due not only to the range and quality of our products but also to the success of our two-drug strategy, giving physicians the choice of both paclitaxel- and everolimus-based DES."

Boston Scientific has the industry's widest range of coronary stent sizes. The TAXUS Liberte Stent Series is now available in 92 sizes, ranging from 2.25 mm to 4.0 mm in diameter and from 8 mm to 38 mm in length.

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.

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 regulatory approvals, 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.

(1) Percentage estimates from April 2009 Millennium Research Group report and ARRIVE 1 and 2 registries.

(2) In the TAXUS ALTAS Long Lesion Trial, the TAXUS Liberte Long (38mm) Stent met its primary endpoint of non-inferiority to the TAXUS Express control Stent in nine-month percent diameter stenosis (31.7% vs. 32.6%, p=0.71) and reported a 36 percent reduction in MACE (9.4% vs. 14.8%, p=0.16).

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