Boston Scientific

Video: Boston Scientific Announces FDA Approval of Second-Generation TAXUS® Liberte® Drug-Eluting Stent

NATICK, Mass., Oct. 10 /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 second-generation TAXUS® Liberte® Paclitaxel-Eluting Coronary Stent System. The Company plans to launch the TAXUS Liberte stent early next month in the United States, following completion of the introduction of its TAXUS® Express2™ Atom™ Paclitaxel-Eluting Coronary Stent System, which was approved by the FDA last month. The TAXUS Liberte stent was launched in Europe and other international markets in 2005.

To view the Multimedia News Release, go to:http://www.prnewswire.com/mnr/bsci/34446/

"The TAXUS Liberte stent represents our latest advance in drug-eluting stent technology," said Donald Baim, M.D., Chief Medical and Scientific Officer of Boston Scientific. "This device has substantially thinner struts and a more flexible cell geometry for improved deliverability, as well as uniform strut distribution designed specifically for drug elution. The TAXUS Liberte stent demonstrated similar late loss and target vessel revascularization (TVR) as the TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System in the ATLAS Workhorse clinical trial, despite treating more challenging patients."

"We believe the approval of TAXUS Liberte is a clear indication that we have made significant progress toward resolving the issues related to the Corporate Warning Letter," said Jim Tobin, President and Chief Executive Officer of Boston Scientific.

The TAXUS stent systems -- both Liberte and Express2 -- 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 4.6 million TAXUS stents have been implanted globally, making them the world's most frequently used drug-eluting stents.

The TAXUS Express2 stent (not the newer TAXUS Liberte stent) was used as the control against the Xience™ V Everolimus-Eluting Coronary Stent System in the SPIRIT II and III trials. XIENCE is a trademark of the Abbott Laboratories group of companies.

The TAXUS Liberte Stent is not available for sale in Japan, where it is undergoing regulatory review.

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 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.

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