Boston Scientific

Boston Scientific Announces FDA Approval for PROMUS™ Everolimus-Eluting Coronary Stent System

PRNewswire-FirstCall
NATICK, Mass.
(NYSE:BSX)

NATICK, Mass., July 2 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that the U.S. Food and Drug Administration (FDA) has approved the PROMUS™ Everolimus-Eluting Coronary Stent System for the treatment of coronary artery disease. The PROMUS Stent is a private-labeled XIENCE™ V Everolimus-Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific under an agreement executed prior to the 2006 acquisition of the former Guidant Corporation by Boston Scientific. FDA approval clears the way for Boston Scientific to launch the PROMUS Stent immediately in the U.S.

The PROMUS Stent expands Boston Scientific's drug-eluting stent (DES) portfolio, which includes the TAXUS® Express2® Paclitaxel-Eluting Coronary Stent System (in the U.S. and international markets) and the TAXUS® Liberte® Paclitaxel-Eluting Coronary Stent System (in international markets), making Boston Scientific the only company to offer physicians the choice of two distinct drugs (paclitaxel and everolimus) on separate DES platforms.

"The PROMUS Stent has shown outstanding deliverability, low late loss and the potential to reduce the need for re-interventions," said Ted Feldman, M.D., F.S.C.A.I., Director of the Cardiac Catheterization Laboratory at Evanston Northwestern Healthcare in Evanston, Illinois. "These benefits will make the PROMUS Stent an attractive new treatment option for U.S. physicians and their patients."

"FDA approval of the PROMUS Stent fulfills Boston Scientific's promise of an unprecedented two-drug strategy - two distinct drugs on two highly deliverable stent platforms," said Jim Tobin, President and Chief Executive Officer of Boston Scientific. "The PROMUS Stent complements our broad DES portfolio and further reinforces Boston Scientific's leadership in the DES market, as well as our commitment to continued innovation and improved patient outcomes."

The next-generation PROMUS Stent is a highly deliverable stent made from cobalt chromium, which allows for thinner struts without sacrificing strength or visibility. The SPIRIT clinical trials indicate that the combination of the polymer/stent platform and the controlled release of the everolimus drug results in excellent deliverability, a strong safety profile, low levels of late loss and improved efficacy, making the PROMUS (XIENCE V) Stent a valuable addition to the U.S. drug-eluting stent market.

Boston Scientific's PROMUS Stent and Abbott's XIENCE V Stent are identical products sold by the respective companies under different brand names. The PROMUS (XIENCE V) Stent is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to de novo native coronary artery lesions (up to 28 mm long) with reference vessel diameter of 2.5 to 4.0 mm.

As a result of agreements related to its acquisition of Guidant in 2006, Boston Scientific shares the rights to everolimus-eluting stent technologies with Abbott, including the XIENCE V Everolimus-Eluting Coronary Stent System (marketed by Boston Scientific as the PROMUS Stent). The Company will continue to market its internally developed paclitaxel-eluting TAXUS Stent Systems, which have been the worldwide DES market leaders, implanted in more than four million people. Boston Scientific is also developing paclitaxel- eluting, everolimus-eluting and bare-metal versions of its third-generation Element™ Stent, which uses a unique platinum-enriched alloy.

The PROMUS Stent is currently for sale in Europe and certain other international markets. TAXUS and PROMUS are trademarks of Boston Scientific Corporation or its affiliates. XIENCE is a trademark of the Abbott Laboratories group of companies. SPIRIT is sponsored by Abbott. The TAXUS Liberte Paclitaxel-Eluting Coronary Stent System is pending approval by the FDA and is not available 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 our product performance, regulatory approval of our products, competitive offerings, our growth strategy, 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 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.

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

Larry Neumann
508-650-8696 (office)
Investor Relations
Boston Scientific Corporation

SOURCE: Boston Scientific Corporation

CONTACT: Media Relations, Paul Donovan, +1-508-650-8541 (office),
+1-508-667-5165 (mobile), or Investor Relations, Larry Neumann,
+1-508-650-8696 (office), both of Boston Scientific Corporation

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

---

https://news.bostonscientific.com/promus-drug-eluting-coronary-stent-system-fda-approval