

Boston Scientific

Boston Scientific Announces Japanese Approval for PROMUS® Everolimus-Eluting Coronary Stent System

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(NYSE:BSX)

NATICK, Mass., Jan. 8 [/PRNewswire-FirstCall/](#) -- Boston Scientific Corporation (NYSE: BSX) announced today that it has received approval from the Japanese Ministry of Health, Labor and Welfare (MHLW) to market its PROMUS® Everolimus-Eluting Coronary Stent System for the treatment of coronary artery disease. The Company plans to launch the product as soon as reimbursement approval is granted, which is expected in the coming weeks.

The PROMUS Stent expands Boston Scientific's drug-eluting stent (DES) portfolio in Japan, which also includes the TAXUS® Liberte® Paclitaxel-Eluting Coronary Stent System. The PROMUS Stent received CE Mark approval in 2006 and U.S. Food and Drug Administration approval in 2008.

Boston Scientific is the only company to offer physicians the choice of two different drugs (paclitaxel and everolimus) on separate DES platforms.

"The approval of the PROMUS Stent in Japan is welcome news for physicians and their patients with coronary artery disease," said Professor Masato Nakamura, Cardiovascular Internal Medicine, Cardiovascular Catheter Treatment Center, Toho University Medical Center in Tokyo. "The safety and efficacy of the PROMUS Stent have been well demonstrated in multiple clinical studies and years of real-world use. The advanced features of this stent make it a valuable addition to the DES treatment options available in Japan."

The PROMUS Stent is a next-generation, highly deliverable stent made from cobalt chromium, which allows for thinner struts without sacrificing strength or visibility. The combination of the polymer/stent platform and the controlled release of the everolimus drug is designed to provide excellent deliverability, a strong safety profile, low levels of late loss and improved efficacy.

"We are very pleased to receive MHLW approval for the PROMUS Stent in Japan," said Maulik Nanavaty, President of Boston Scientific Japan. "It complements our broad coronary intervention portfolio and reinforces our global leadership in the DES market. We remain committed to providing the most innovative products and therapies to the Japanese market."

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. The PROMUS and XIENCE V Stents are identical products sold by the respective companies under different brand names.

Boston Scientific will continue to market its internally developed paclitaxel-eluting TAXUS Stent Systems. To date, more than six million TAXUS and PROMUS Stents have been implanted globally, making Boston Scientific the worldwide DES market leader.

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 3.75 mm.

TAXUS and PROMUS are trademarks of Boston Scientific Corporation or its affiliates. XIENCE is a trademark of the Abbott Laboratories group of companies.

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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