

Boston Scientific Announces FDA Approval and U.S. Launch of PROMUS® 2.25 mm Everolimus-Eluting Coronary Stent System

NATICK, Mass., May 25, 2011 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced it has received approval from the U.S. Food and Drug Administration (FDA) to market its 2.25 mm [PROMUS® Everolimus-Eluting Coronary Stent System](#) for use in vessels as small as 2.25 mm in diameter. The Company plans to immediately launch the product in the U.S.

The PROMUS Stent features a thin-strut, open-cell design to allow for excellent flexibility and conformability in the vessel. The low-profile stent and catheter tip help enhance deliverability, especially in small vessels. The PROMUS Stent is supported by the SPIRIT clinical trial program, which demonstrates that the controlled release of everolimus results in low levels of late loss and a strong safety profile. The addition of this stent expands the available size matrix of Boston Scientific's PROMUS Stent portfolio to include diameters from 2.25 to 4.0 mm and lengths from 8 mm to 28 mm.

"The PROMUS Stent has demonstrated outstanding deliverability, low late loss and excellent safety in numerous clinical trials and extensive real-world practice," said Dean J. Kereiakes, M.D., FACC, Medical Director, The Christ Hospital Heart and Vascular Center and The Carl and Edyth Lindner Center for Research and Education at The Christ Hospital, and Professor of Clinical Medicine, Ohio State University. "These benefits make the PROMUS 2.25 mm Stent an attractive option for U.S. physicians treating patients with small vessels."

"The approval of the 2.25 mm PROMUS Stent further expands our leading drug-eluting stent portfolio, which includes both everolimus and paclitaxel-eluting stents for the treatment of small vessels and long lesions," said Hank Kucheman, Executive Vice President and Group President, Cardiology, Rhythm and Vascular for Boston Scientific. "In 2008, we became the first company to introduce a dedicated small-vessel stent and have led this segment ever since. An everolimus-based, small-vessel stent allows physicians even greater flexibility in treating a variety of complex coronary lesions."

Data from clinical studies have shown that an estimated 10 percent of patients undergoing percutaneous coronary interventions have small vessels (<2.5 mm). The 2.25 mm PROMUS Stent joins the 2.25 mm ION™ Paclitaxel-Eluting Platinum Chromium Stent as the Company's approved drug-eluting stenting options for small vessels.

The PROMUS Stent is a private-labeled XIENCE V® Everolimus-Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific. PROMUS is a trademark of Boston Scientific Corporation or its affiliates. XIENCE V is a trademark of the Abbott Laboratories group of companies. The SPIRIT clinical trials are sponsored by Abbott.

About Boston Scientific

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 27A of the Securities Act of 1933 and 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 new product launches and launch cadence, markets for our products and our market position in segments of those markets, 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 hereafter. 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: Erik Kopp

508-650-8660 (office)

Media Relations

Boston Scientific Corporation

erik.kopp@bsci.com

Sean Wirtjes

508-652-5305 (office)

Investor Relations

Boston Scientific Corporation

investor_relations@bsci.com

SOURCE Boston Scientific Corporation

<https://news.bostonscientific.com/promus-everolimus-eluting-stent-launch-usa>