

Boston Scientific

Boston Scientific Announces FDA Approval of TAXUS® Express2™ Atom™ Stent System, First Drug-Eluting Stent For Small Vessels
Company also announces FDA approval of TAXUS® Express2™ Stent System for treatment of in-stent restenosis

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NATICK, Mass.
(NYSE:BSX)

NATICK, Mass., Sept. 25 /[PRNewswire-FirstCall](#)/ -- Boston Scientific Corporation (NYSE: BSX) today announced that it has received approval from the U.S. Food and Drug Administration (FDA) to market its TAXUS® Express2™ Atom™ Paclitaxel-Eluting Coronary Stent System. The TAXUS Express Atom Stent is a highly deliverable drug-eluting stent (DES) specifically designed for treating small coronary vessels. It is the only DES approved by the FDA for use in vessels as small as 2.25 mm in diameter. No other DES for sale in the U.S. market is approved for use in vessels smaller than 2.50 mm in diameter. The Company plans to launch the product immediately.

The Company today also announced FDA approval of its TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System for the treatment of in-stent restenosis in bare-metal stents. This is the first such approval granted by the FDA, making the TAXUS Express2 Stent System the only drug-eluting stent approved in the United States for the treatment of in-stent restenosis in bare-metal stents.

"The TAXUS Express Atom Stent will provide better options for U.S. patients with coronary artery disease in small vessels," said Gregg Stone, M.D., Chairman of the Cardiovascular Research Foundation and Professor of Medicine at Columbia University Medical Center, and Principal Investigator of the TAXUS IV and V clinical trials. "This is a welcome addition to the range of available drug-eluting stents, since patients with small vessels who are currently treated with bare-metal stents experience high rates of restenosis. In the TAXUS V clinical trial, the TAXUS Express Atom Stent significantly reduced the chance of restenosis and the need for repeat procedures compared to bare-metal stents, in patients with small vessel disease."

"Our TAXUS Express Atom Stent addresses an unmet need and will help interventional cardiologists better treat small vessel disease," said Jim Tobin, President and Chief Executive Officer of Boston Scientific. "With the recent FDA approval of our PROMUS™ Stent and now the TAXUS Express Atom Stent for small vessels, Boston Scientific offers the most comprehensive DES portfolio in the industry, offering physicians and their patients the broadest size matrix and the industry's only two-drug platform."

"In addition to being a welcome product approval, we believe this is also an important indication we have made significant progress toward resolving the issues related to the Corporate Warning Letter," added Tobin.

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 4.6 million TAXUS stents have been implanted globally, making them the world's most frequently used drug-eluting 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: <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 clinical trials, product performance, competitive offerings, procedural volume, overall market size 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: Paul Donovan, Media Relations, +1-508-650-8541, +1-508-667-5165 (mobile), or Larry Neumann, Investor Relations, +1-508-650-8696, both of Boston Scientific Corporation

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

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