Boston Scientific

FDA Approves Boston Scientific's Next-Generation TAXUS® Liberte® Atom™ Stent System

PRNewswire
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(NYSE:BSX)

NATICK, Mass., May 27 /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 TAXUS® Liberte® Atom™ Paclitaxel-Eluting Coronary Stent System, a highly deliverable, next-generation drug-eluting stent (DES) specifically designed for treating small coronary vessels. It was approved for use in vessels as small as 2.25 mm in diameter and joins the TAXUS® Express® Atom™ Stent as the only drug-eluting stents approved for small vessel use in the U.S. The Company plans to begin a full U.S. launch of TAXUS Liberte Atom next month.

"The rapid adoption of the TAXUS Express Atom Stent has confirmed the need for this type of stenting option in the treatment of small-vessel coronary artery disease," said Mark Turco, M.D., F.A.C.C., F.S.C.A.I., Director of the Center for Cardiac and Vascular Research at Washington Adventist Hospital, Takoma Park, Maryland. "The TAXUS Liberte Atom Stent provides clear design and deliverability advantages. Additionally, in the TAXUS Atlas Small Vessel clinical trial, the TAXUS Liberte Atom Stent yielded a two-year target lesion revascularization rate that was 60 percent less than the TAXUS Express Atom Stent. I am pleased to be able to offer this option to my patients."

Data from numerous clinical studies have shown that an estimated 10percent of patients undergoing percutaneous coronary interventions have small vessels (<2.5 mm). Until recently, many physicians were inclined to implant bare-metal stents in these patients since they were the only approved stenting option for small vessels. Last year's launch of the TAXUS Express Atom Stent offered an alternative treatment choice for patients with small vessels who will now have the additional option of the TAXUS Liberte Atom Stent.

The TAXUS Liberte Stent features design improvements over the Company's first-generation TAXUS Express Stent, including thinner struts to allow better stent deliverability and conformability, as well as uniform stent geometry for consistent lesion coverage and drug distribution.

Boston Scientific offers the industry's widest range of coronary stent sizes. The Company expects to expand its stent portfolio later this year with the first 38 mm long DES, the TAXUS® Liberte® Long Stent, which is currently under review with the FDA.

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 11 million Boston Scientific stents have been implanted globally, making them the world's most frequently used 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: 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.

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