Boston Scientific

Boston Scientific Submits Final Modules to FDA for Approval of Second-Generation Small Vessel and Long Lesion Stents

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Journal of American College of Cardiology publishes positive ATLAS clinical data

NATICK, Mass., Feb. 5 /PRNewswire-FirstCall/ -- Boston Scientific Corporation today announced that it has submitted to the U.S. Food and Drug Administration (FDA) the final modules of the Company's Pre-Market Approval (PMA) applications for both its TAXUS® Liberte® Atom™ Paclitaxel-Eluting Coronary Stent System and its TAXUS Liberte Long™ Paclitaxel-Eluting Coronary Stent System. If approved, the TAXUS Liberte Atom Stent will become the Company's second 2.25 mm diameter drug-eluting stent (DES) available in the United States. It will then likely succeed the TAXUS Express™ Atom Stent, which is the Company's first approved small stent and the only DES currently approved by the FDA to treat small vessels. The TAXUS Liberte Long Stent is designed to be the first 38 mm drug-eluting stent available in the U.S. and will further expand the Company's leading DES portfolio.

These PMA submissions include clinical data from the global, multi-center TAXUS ATLAS Small Vessel (SV) and Long Lesion (LL) studies, designed to compare the performance of the TAXUS Liberte Atom and TAXUS Liberte Long Stents with Boston Scientific's first-generation TAXUS Express Stent. While the second-generation TAXUS Liberte Stent uses identical drug dose, polymer and release kinetics as the TAXUS Express Stent, it features thinner struts and a uniform architecture specifically designed for drug delivery.

One-year results from the TAXUS ATLAS SV and LL studies were published in the December 2008 issue of the Journal of American College of Cardiology. The studies both met their primary endpoint of non-inferior, nine-month, in-segment diameter stenosis versus the TAXUS Express Stent control group. They reported a significant reduction in small vessel in-stent restenosis and major adverse coronary events (MACE) in patients treated with the TAXUS Liberte Atom Stent, and a significantly reduced rate of myocardial infarction (heart attack) in patients with long lesions treated with the TAXUS Liberte Long Stent.

"In the ATLAS study, lower target lesion revascularization (TLR) rates contributed to a significantly lower rate of MACE, including heart attacks, with the TAXUS Liberte Atom Stent," said Mark A. Turco, M.D., Director of the Center for Cardiac and Vascular Research, Washington Adventist Hospital, and Co-Principal Investigator of the ATLAS trial. "The thinner struts of the TAXUS Liberte Atom Stent are designed to improve its deliverability and conformability, which is important when treating small vessels. The TAXUS Liberte Stent also features an advanced stent cell geometry that has been designed to allow for more consistent drug distribution."

Patients with small vessels treated with the TAXUS Liberte Atom Stent reported significantly lower nine-month angiographic in-segment late loss (0.16 mm vs. 0.32 mm, p=0.0146), reduced nine-month angiographic restenosis (18.5% vs. 32.7%, p=0.0219), reduced 12-month TLR (6.1% vs. 16.9%, p=0.0039), and reduced rates of stent thrombosis (0.4% vs. 1.5%, p=0.39). Patients with long lesions treated with the TAXUS Liberte Long Stent reported a significantly reduced 12-month rate of myocardial infarction (1.4% vs. 6.5%, p= 0.0246) as well as a trend toward fewer stent thromboses (0% vs. 0.7%, p=0.48).

"We are pleased to have a second-generation small vessel DES and the U.S. market's first long DES under review by the FDA," said Jim Tobin, President and Chief Executive Officer of Boston Scientific. "The rapid adoption of our recently approved TAXUS Express Atom Stent confirms the need for an expanded DES size matrix to treat the wide range of vessel anatomies seen in daily clinical practice."

Boston Scientific remains the overall drug-eluting stent market leader in the United States, with a 49 percent share of the market in December. The Company released three major DES products in the United States in 2008 with the PROMUS® Everolimus-Eluting Coronary Stent, the TAXUS Express Atom Stent and the TAXUS Liberte Stent. The Company expects to launch its third-generation drug-eluting stents -- the TAXUS Element™ Paclitaxel-Eluting Coronary Stent and the PROMUS Element Everolimus-Eluting Coronary Stent -- in Europe later this year.

The TAXUS Liberte Atom, TAXUS Liberte Long, TAXUS Element and PROMUS Element stents are investigational devices and are restricted under U.S. law to investigational use only.

The PROMUS® Stent is a private-labeled XIENCE™ V Everolimus-Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific. XIENCE™ V 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: 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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