Boston Scientific

TAXUS® Liberte™ Drug-eluting Coronary Stent System Receives CE Mark for Use in Diabetic Patients

NATICK, Mass., Dec. 21 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) announced today that its TAXUS® Liberte™ paclitaxel-eluting coronary stent system has received European CE Mark approval for use in patients with diabetes.(1) Boston Scientific submitted data showing the TAXUS Liberte stent has benefited diabetic patients with coronary artery disease, both in clinical trials and real-world registries. This approval means the TAXUS Liberte stent system now has more CE Mark- approved indications than any other drug-eluting stent, allowing treatment of a wide range of patients including many of those at high risk. The TAXUS Liberte stent system is the most frequently used drug-eluting stent system in Europe.

"Achieving CE Mark approval for TAXUS Liberte in patients with diabetes is an important milestone," said David McFaul, Boston Scientific Senior Vice President, International. "As a leader in devices for the treatment of cardiovascular disease, Boston Scientific's goal is to provide patients with the most advanced treatment options available. In this case, we are offering another specific solution for diabetic patients outside the United States, who are typically at higher risk for adverse events compared to non-diabetic patients."

Combined data from four TAXUS ATLAS trials supported the efficacy and safety of the TAXUS Liberte stent system in diabetic patients.(2) The trials examined 1,529 patients treated with the TAXUS Liberte stent system, 413 of whom had diabetes, and reported similar rates of target lesion revascularization (TLR, or retreatment), cardiac death, myocardial infarction (MI, or heart attack) and stent thrombosis (clotting) between diabetic and non-diabetic stent recipients after adjustment for differences in risk at baseline.

Diabetes affects more than 200 million people worldwide and is expected to affect 360 million people by 2030.(3) Approximately half of all patients presenting with coronary artery disease (CAD) in Europe have diabetes.(4) Diabetic patients with CAD often have poorer outcomes after revascularization procedures because their blood vessels tend to build up more plaque than the vessels of non-diabetic patients, and their CAD advances more quickly. CAD is the most common cause of death among European adults with diabetes.(5)

As a result of the expanded CE Mark, the TAXUS Liberte stent system in the European Union is indicated for treatment of de novo and restenotic lesions or total occlusions in patients with coronary artery disease -- angina; silent ischemia; acute myocardial infarction -- to improve luminal diameter and reduce restenosis within the stent and at the stent edges in native coronary arteries. The TAXUS Liberte stent system is also indicated for patients with concomitant diabetes mellitus as well as treatment of abrupt or threatened closure in patients with failed interventional therapy.

The TAXUS Liberte stent is available outside the United States in a wide range of sizes to treat a diversity of vessel sizes and lesion lengths seen in patients with coronary artery disease.

The TAXUS Liberte stent system is pending approval by the U.S. Food and Drug Administration and is not available for sale in the United States.

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-international.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 our product performance, regulatory approval of our products, competitive offerings, our growth strategy, 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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