Boston Scientific

Boston Scientific Receives Industry's First FDA Approval for Drug-Eluting Coronary Stent Use in Heart Attack Patients

NATICK, Mass., Feb. 22, 2012 /PRNewswire/ -- Boston Scientific Corporation's (NYSE: BSX) ION™ Paclitaxel-Eluting Platinum Chromium Coronary Stent System and TAXUS® Liberte® Paclitaxel-Eluting Coronary Stent System have received U.S. Food and Drug Administration (FDA) approval for use in patients experiencing an acute myocardial infarction (AMI), or heart attack. They are the only drug-eluting stent (DES) systems in the U.S. with an approved indication to treat patients with AMI.

The new indication, which accounts for approximately 10 percent of all coronary interventions, is a result of FDA review of data from the Paclitaxel (TAXUS) clinical program and HORIZONS-AMI trial. In the global HORIZONS-AMI trial, 3,006 patients were randomized to receive either drug-eluting stents or bare-metal stents for the treatment of AMI, making it the largest randomized trial to study coronary stents in heart attack patients.

"The AMI indication is a testament to our long-term commitment to innovation and leading clinical science in support of advanced DES technologies," said Keith D. Dawkins, M.D., Global Chief Medical Officer for Boston Scientific. "Clinical data from the HORIZONS-AMI trial showed that, in patients with AMI, paclitaxel-eluting stents were superior in efficacy to bare-metal stents, significantly reducing clinical and angiographic restenosis compared to bare-metal stents, while demonstrating a comparable safety profile at three years. We are proud that our investments in randomized trials such as HORIZONS-AMI have led to the approval of products to treat a broader range of patients with coronary artery disease."

"The new indication for heart attack patients should give U.S. physicians the confidence to treat this high-risk group with Boston Scientific's advanced paclitaxel-eluting stent technology backed by a robust clinical program that spans 10 years of research," said Hank Kucheman, Chief Executive Officer of Boston Scientific. "The AMI indication reinforces the safety and effectiveness of the ION and TAXUS Liberte paclitaxel-eluting stents in treating challenging patients and lesions in both clinical and real-world practice. The inclusion of the ION Stent for this indication should be welcome news for physicians and patients. This innovative platinum chromium stent has been very well received since its U.S. launch last year based on its exceptional visibility, radial strength and deliverability."

The Company's ION Stent System incorporates a unique platinum chromium (PtCr) alloy designed specifically for coronary stenting and intended to improve the acute performance of coronary stent implantation in the treatment of coronary artery disease.

The American Heart Association estimates that death by heart attack accounts for one out of every six deaths annually in the U.S. There are more than 1.2 million new and recurrent cases of heart attack each year, with approximately 34 percent resulting in death.(1)

About Boston Scientific

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices that 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, regulatory approvals, clinical trials, markets for our products, product performance and acceptance 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.

(1) Source: American Heart Association

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