

Study Shows Superior Efficacy for TAXUS® Express® Stents at One Year Compared to Bare-Metal Stents in Diabetic Patients Experiencing Heart Attack

Boston Scientific applies to FDA for expanded indications for TAXUS Express and TAXUS® Liberte® Stents in AMI patients

NATICK, Mass. and ATLANTA, March 15 [PRNewswire-FirstCall](#)/ -- Boston Scientific Corporation (NYSE: BSX) today announced results from an analysis of one-year subset data from the HORIZONS AMI trial assessing the impact of diabetes on clinical and angiographic outcomes in heart attack patients treated with the TAXUS® Express2™ Paclitaxel-Eluting Stent System or the Express® bare-metal stent. The results demonstrated that the TAXUS® Express® Stent significantly reduced ischemia-driven target lesion revascularization (TLR) at one year and binary in-stent restenosis at 13 months in diabetic patients experiencing an acute myocardial infarction (AMI, or heart attack) compared to an otherwise identical bare-metal control stent. Analysis of the data was presented today at the American College of Cardiology Annual Scientific Sessions by Bernhard Witzenbichler, M.D., Department of Cardiology and Pneumology, Universitätsmedizin Berlin.

The Company also announced it has submitted an application to the U.S. Food and Drug Administration (FDA) requesting expansion of the indications for use of the TAXUS Express and TAXUS® Liberte® Stents to include patients experiencing AMI.

"Results from the HORIZONS AMI trial showed impressive efficacy benefits at one year for diabetic AMI patients treated with the TAXUS Express Stent when compared to bare-metal stents," said Keith Dawkins, M.D., Senior Vice President and Chief Medical Officer for Boston Scientific. "The data also showed comparable safety outcomes for TAXUS Express and bare-metal stents in diabetic patients. This study provides important data to physicians regarding the use of drug-eluting stents in high-risk AMI patients, especially those with diabetes, during the early hours of a heart attack. We are proud to support this and other large clinical trials that provide the medical community data that can be used in combination with broader clinical judgment to develop optimal treatment strategies for challenging patient subsets."

HORIZONS AMI results demonstrated that the TAXUS Express Stent significantly reduced ischemia-driven TLR compared to the bare-metal control stent (BMS) in both diabetic patients (5.2% vs. 11.2%, $p=0.03$, a 54 percent reduction), and non-diabetic patients (4.3% vs. 6.8%, $p=0.02$, a 37 percent reduction). Binary in-stent restenosis at 13 months was also significantly reduced for diabetic patients treated with the TAXUS Express Stent compared to BMS (8.2% vs. 43.9%, $p<0.0001$, an 81 percent reduction). Additionally, mean angiographic late loss at 13 months was significantly reduced for diabetic patients treated with the TAXUS Express Stent compared to BMS (0.38 mm vs. 1.13 mm, $p<0.0001$, a 66 percent reduction).

The primary safety measure of major adverse cardiac events (MACE) at one year was comparable between diabetic patients treated with the TAXUS Express Stent and BMS (10.2% vs. 12.5%, $p=0.18$), which is consistent with one-year findings from the overall HORIZONS AMI patient population. Rates of death or repeat heart attack at one year were also comparable for diabetic patients between the two treatment groups (8.8% vs. 10.7%, $p=0.56$). Stent thrombosis rates using the Academic Research Coalition (ARC) definite/probable definition were statistically similar for diabetic patients treated with the TAXUS Express Stent and BMS (3.1% vs. 4.5%, $p=0.49$).

Heart attack patients are often treated with bare-metal stents and are a more complicated patient population with known increased risks for death and stent thrombosis. Additionally, diabetic patients generally have more long-term complications than interventional cardiology patients as a whole, and account for more than one-quarter of all coronary interventional procedures in the United States. The diabetic subset population in the HORIZONS AMI trial presented with more complex baseline characteristics than non-diabetic patients, including significantly higher measures of weight, hypertension, peripheral vascular disease, renal insufficiency, prior MI, prior percutaneous coronary intervention and prior coronary artery bypass graft surgery.

With 3,006 patients enrolled worldwide, HORIZONS AMI is the largest randomized trial to compare the use of drug-eluting stents to bare-metal stents in AMI patients.

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, regulatory approvals, competitive offerings and product performance. 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.

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