

HORIZONS-AMI Trial Provides Superior Outcomes Data at Three Years with TAXUS® Drug-Eluting Stent in Heart Attack Patients

NATICK, Mass., Sept. 25 [PRNewswire](#)/ -- Boston Scientific Corporation (NYSE: BSX) today announced three-year follow-up data from the HORIZONS-AMI trial. The trial, sponsored by the Cardiovascular Research Foundation (CRF) with grant support from Boston Scientific and The Medicines Company (Nasdaq: MDCO), is designed to determine the safety and efficacy of the TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System compared to bare-metal stenting in patients experiencing an acute myocardial infarction (AMI), or heart attack. 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 for AMI patients. Analysis of the data was presented by Gregg W. Stone, M.D., Professor of Medicine and the Director of Research and Education at the Center for Interventional Vascular Therapy at the Columbia University Medical Center/New York-Presbyterian Hospital and Principal Investigator of the trial, at CRF's annual Transcatheter Cardiovascular Therapeutics scientific symposium in Washington, D.C.

"Follow-up data from the HORIZONS-AMI trial continue to show that, in patients with AMI, paclitaxel-eluting stents were superior in efficacy to bare-metal stents and had a comparable safety profile," said Dr. Stone. "Significant reductions in measures of re-intervention at three years were observed with no evidence of late catch-up."

HORIZONS-AMI demonstrated that the TAXUS Express Stent significantly reduced clinical and angiographic restenosis compared to an otherwise identical bare-metal Express® control stent. After three years follow-up, the primary efficacy endpoint of ischemia-driven target lesion revascularization (TLR) was 9.4 percent for patients treated with TAXUS Express vs. 15.1 percent for bare-metal Express ($p < 0.001$), a relative reduction of 40 percent. The secondary efficacy endpoint of ischemia-driven target vessel revascularization (TVR) was 12.4 percent for TAXUS Express vs. 17.6 percent for bare-metal Express ($p < 0.001$), a relative reduction of 32 percent.

The primary safety endpoint of major adverse cardiac events (MACE) at three years was comparable for TAXUS Express and bare-metal Express patients (13.6 percent vs. 12.9 percent, respectively, $p = 0.66$), which is consistent with findings at one and two years. Individual rates of death, repeat heart attack, stroke and stent thrombosis between the two groups through three years of follow-up were also comparable.

"Results from the HORIZONS-AMI trial continue to show the impressive benefits of paclitaxel-eluting stent technology in this important high-risk AMI patient population," said Keith D. Dawkins, M.D., Senior Vice President and Chief Medical Officer for Boston Scientific's Cardiology, Rhythm and Vascular Group. "Boston Scientific continues to support 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."

The TAXUS Express Stent and the Express Stent are not specifically indicated by the U.S. Food and Drug Administration for use in patients with AMI.

About Boston Scientific

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 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, 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 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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