

Boston Scientific

Study Shows Superior Efficacy for TAXUS® Express® Stents Compared to Bare-Metal Stents in Heart Attack Patients at Two Years

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(NYSE:BSX)

NATICK, Mass. and SAN FRANCISCO, Sept. 25 [PRNewswire-FirstCall/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced two-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 (DES) to bare-metal stents (BMS) for AMI patients. Analysis of the data was presented today at the 21st annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in San Francisco.

"Results from the HORIZONS-AMI trial showed impressive and sustained efficacy benefits at two years for patients treated with TAXUS Express Stents when compared to bare-metal stents in patients with AMI," said 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. "The data also showed comparable safety outcomes for the TAXUS Express and bare-metal stents. This study should continue to inform how decisions are made regarding the use of drug-eluting stents in high-risk AMI patients during the early hours of a heart attack."

HORIZONS-AMI demonstrated that the TAXUS Express Stent significantly reduced angiographic restenosis compared to an otherwise identical bare-metal Express® control stent. After two years follow-up, the primary efficacy endpoint of ischemia-driven target lesion revascularization (TLR) was 6.8 percent for patients treated with DES vs. 11.6 percent for BMS ($p<0.001$), a reduction of 42 percent. The secondary efficacy endpoint of ischemia-driven target vessel revascularization (TVR) was 8.9 percent for DES vs. 13.3 percent for BMS ($p<0.001$), a reduction of 34 percent.

The primary safety endpoint of major adverse cardiac events (MACE) at two years was comparable among DES and BMS patients (11.0 percent vs. 11.2 percent, respectively, $p=0.90$), which is consistent with one-year findings. Individual rates of death, repeat heart attack, stroke and stent thrombosis between the two groups through two years of follow-up were also comparable, even after correction for any measured baseline differences. Adverse events between one and two years showed that all-cause death was lower among DES patients (0.8 percent DES vs. 1.8 percent BMS, $p=0.04$), ischemia-driven TLR was lower among DES patients (2.6 percent DES vs. 4.7 percent BMS, $p=0.006$), and ischemia-driven TVR showed similar lower rates with DES compared to BMS (3.4 percent DES vs. 5.2 percent BMS, $p=0.03$).

"HORIZONS-AMI results continue to highlight the value of the TAXUS Express Stent in this important high-risk AMI patient population," said Keith D. Dawkins, M.D., Associate Chief Medical Officer of Boston Scientific. "The reductions in TLR, TVR and mortality with DES compared to BMS between one and two years suggest improving safety measures that warrant further investigation. 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."

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.

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 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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