Boston Scientific

Boston Scientific Welcomes Publication of HORIZONS AMI Trial Results in New England Journal of Medicine

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Data from landmark trial provide important insight for physicians in treating heart attack patients

NATICK, Mass., May 6 /PRNewswire-FirstCall/ -- Boston Scientific Corporation today welcomed the publication of results from the HORIZONS AMI trial in this week's issue of the New England Journal of Medicine. The HORIZONS AMI trial, sponsored by the Cardiovascular Research Foundation with research grant support from Boston Scientific and The Medicines Company , is designed to evaluate the safety and efficacy of the TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System compared to bare-metal stenting in patients undergoing catheter treatment for an acute myocardial infarction (AMI), or heart attack.

With more than 3,000 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 the treatment of heart attack patients, a complicated patient population with known increased risks of death and stent thrombosis. The one-year results demonstrated that the TAXUS Express Stent significantly reduced angiographic restenosis and the primary efficacy endpoint of ischemia-driven target lesion revascularization (TLR, or rate of re-intervention of the stented segment) compared to an otherwise identical bare-metal Express® Stent control. The primary safety measure showed no difference between the TAXUS Express Stent and the bare-metal Express Stent in overall major adverse cardiovascular events (MACE), or its components, including death, repeat heart attack, stroke or stent thrombosis at one year.

"The HORIZONS AMI trial provided outcomes data showing treatment with a TAXUS paclitaxel-eluting stent had superior efficacy measures when compared to a bare-metal stent in patients with AMI, while demonstrating a comparable safety profile," 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.

"This is the first prospective, global randomized clinical trial sufficiently powered to provide conclusive data comparing DES and BMS in heart attack patients," continued Dr. Stone. "The findings from the HORIZONS AMI trial should have a major impact on how decisions are made regarding the use of drug-eluting stents in these high-risk patients during the early hours of a heart attack. This study provides much needed data, and the patients in this trial will be followed for five years to determine if these favorable results are maintained."

"Boston Scientific is proud to support this and other large clinical trials that provide the medical community with relevant data that can be used in combination with broader clinical judgment to develop optimal treatment strategies for challenging patient subsets," said Donald S. Baim, M.D., Chief Medical and Scientific Officer of Boston Scientific. "The HORIZONS AMI trial provides valuable insight into the benefits of the TAXUS paclitaxel-eluting stent compared to bare-metal stents, in this important high-risk AMI patient population."

One-year results from the HORIZONS AMI trial showed ischemia-driven TLR was reduced by 41 percent with DES compared to BMS (4.5% vs. 7.5%, p=0.002), with parallel reduction in ischemia-driven target vessel revascularization (TVR) among patients treated with DES (5.8% vs. 8.7%, p=0.006). Angiographic follow-up at 13 months was available for 910 DES patients (1,081 lesions) and 293 BMS patients (332 lesions), and showed a 56 percent reduction in the secondary efficacy endpoint of binary restenosis, from 22.9 percent among lesions in the BMS group to 10.0 percent among lesions in the DES group (p<0.001). This restenosis benefit was due to a significant reduction of in-stent late loss for DES lesions compared to BMS (0.41 +/- 0.64 mm vs. 0.82 +/- 0.70 mm, p<0.001).

The primary safety endpoint of MACE at one year was comparable among DES and BMS patients (8.1% vs. 8.0%, respectively, p=0.92), with comparable individual rates of death, repeat heart attack, stroke and stent thrombosis between the two groups through 12 months of follow-up, which persisted even after correction for any measured baseline differences.

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.

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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, 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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