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

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NATICK, Mass., Feb. 22, 2012 /PRNewswire/ -- Boston Scientific Corporation's (NYSE: BSX [1]) 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 ro
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