

Boston Scientific Completes Enrollment in EVOLVE Clinical Trial to Evaluate SYNERGY™ Drug-Eluting Coronary Stent

NATICK, Mass., Jan. 24, 2011 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced the completion of patient enrollment in the EVOLVE clinical trial, which is designed to assess the safety and performance of the Company's fourth-generation SYNERGY™ Coronary Stent. The randomized, single-blind, non-inferiority trial will compare the SYNERGY Stent to the PROMUS Element™ Everolimus-Eluting Coronary Stent in patients with a single *de novo* native coronary artery lesion. The trial enrolled 291 patients at 29 sites in Europe, Australia and New Zealand, and completed enrollment four months ahead of schedule.

The SYNERGY Stent uses a bioabsorbable PLGA polymer and everolimus drug combination to create a thin, uniform coating confined to the outer surface of the stent. Once the drug has been delivered, the bioabsorbable coating resorbs in three to six months, leaving behind only a bare-metal stent. This technology is designed to provide the same degree of restenosis reduction as a conventional drug-eluting stent while offering faster and more complete vessel healing after stent implantation, which could potentially reduce the duration of required adjunctive medical therapies. The SYNERGY Stent features the same proprietary platinum chromium alloy and innovative stent design used in the PROMUS Element Stent to enable thinner struts, increased flexibility and a lower profile while reducing recoil and improving radial strength and visibility.

"We are pleased to complete the enrollment phase of the EVOLVE clinical trial well ahead of schedule," said Professor Ian Meredith, M.B.B.S., Ph.D., Director of MonashHeart, Monash Medical Centre, Melbourne, Australia, and Principal Investigator of the trial. "The brisk pace of enrollment reflects the strong interest in this innovative drug-eluting stent technology that could play an important role in helping reduce adverse events including late stent thrombosis."

"The SYNERGY Stent is designed to combine the acute performance advantages of the platinum chromium PROMUS Element Stent with an innovative bioabsorbable drug-polymer combination," said Keith D. Dawkins, M.D., Senior Vice President and Chief Medical Officer of Boston Scientific's Cardiology, Rhythm and Vascular Group. "We believe this technology will represent a significant advance for drug-eluting stents by reducing the amount of polymer and drug to which the vessel wall is exposed, while eliminating the coating on the inner surface of the stent where endothelial cell growth is required for healing."

The EVOLVE trial compares two doses of everolimus on the SYNERGY Stent (a PROMUS Element equivalent dose and a dose half that amount) randomized against a commercially available PROMUS Element Stent. The primary clinical endpoint is target lesion failure at 30 days, a composite measure of cardiac death, myocardial infarction and target lesion revascularization. The primary angiographic endpoint is in-stent late loss at six months as measured by quantitative coronary angiography (QCA). Patients will also be assessed by intravascular ultrasound (IVUS) at the time of initial procedure and at six months. Data from the trial will be used to support CE Mark approval for the SYNERGY Stent.

"Completion of enrollment brings our fourth-generation drug-eluting stent platform another step closer to commercialization," said Hank Kucheman, Executive Vice President and President of Boston Scientific's Cardiology, Rhythm and Vascular Group. "The SYNERGY Stent demonstrates our commitment to innovation and clinical science in pursuit of the most advanced treatment options for our physicians and their patients. We are confident that the SYNERGY Stent will enhance our leading drug-eluting stent portfolio."

In the U.S., the SYNERGY Stent and the PROMUS Element Stent are investigational devices and are limited by applicable law to investigational use only and are not available for sale. The Company received CE Mark approval for the PROMUS Element Stent in October 2009.

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.

CONTACT: Paul Donovan

508-650-8541 (office)

508-667-5165 (mobile)

Media Relations

Boston Scientific Corporation

Larry Neumann

508-650-8696 (office)

Investor Relations

Boston Scientific Corporation

Sean Wirtjes

508-652-5305 (office)

Investor Relations

Boston Scientific Corporation

SOURCE Boston Scientific Corporation

<https://news.bostonscientific.com/synergy-drug-eluting-stent-clinical-trial-enrollment>