Boston Scientific Begins Clinical Trial Enrollment for New Coronary Stent with Bioabsorbable Polymer and Everolimus Drug Coating

Boston Scientific

NATICK, Mass., Aug. 3 /PRNewswire-FirstCall [1]/ -- Boston Scientific Corporation (NYSE: BSX) today announced the start of patient enrollment in the EVOLVE clinical trial, which is designed to assess the safety and performance of its fourth-generation SYNERGY™ Coronary Stent. The first patient was enrolled by Ian Meredith, M.B.B.S., Ph.D., Professor and Director of MonashHeart, at Monash Medical Centre in Melbourne, Australia.

The SYNERGY Stent uses a bioabsorbable PLGA polymer and everolimus drug formulation to create a thin, uniform coating confined to the outer surface of the stent. Once the drug has been delivered, the bioabsorbable coating resorbs into the body, 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. 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 improving radial strength, recoil and visibility.

EVOLVE is a randomized, single-blind, non-inferiority clinical trial that will enroll 291 patients at up to 35 sites in Europe, Australia and New Zealand. The 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. Two drug doses will be evaluated with the SYNERGY Stent, including an everolimus dose approximately equal to that of the PROMUS Element Stent and a dose equivalent to half that amount. 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). Clinical follow-up will occur at 30 days, six months, nine months, and every 12 months out to five years. In addition, all patients will undergo intravascular ultrasound at the time of initial procedure and at six months. Patient enrollment in the trial is scheduled to be completed by mid 2011. Data from the trial will be used to support CE Mark approval for the SYNERGY Stent.

Principal Investigators for the trial are Prof. Meredith and Stefan Verheye, M.D., Ph.D., Department of Interventional Cardiology, Middelheim Hospital in Antwerp, Belgium.

"We are pleased to enroll the first patient in the EVOLVE trial to evaluate this innovative new coronary stent technology," said Prof. Meredith. "I am enthusiastic

about the possibility of having an everolimus stent that minimizes the initial polymer coating, provides a bare luminal surface, and becomes a bare-metal stent after a few months once drug delivery is complete. This type of treatment option could play an important role in helping reduce adverse events such as late stent thrombosis."

"While some companies are still evaluating their first- or second-generation drug-eluting stent technology, we are proud to begin clinical trials on our fourth-generation stent," said Keith Dawkins, M.D., Senior Vice President and Chief Medical Officer of Boston Scientific's Cardiology, Rhythm and Vascular Group. "The SYNERGY Stent is designed to significantly reduce 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 SYNERGY Stent is designed to combine the acute performance advantages of the platinum chromium PROMUS Element Stent with an innovative bioabsorbable polymer," said Hank Kucheman, Executive Vice President and President of Boston Scientific's Cardiology, Rhythm and Vascular Group. "We believe this technology will represent a significant advance for drug-eluting stents and should help us maintain our global leadership position in the drug-eluting stent market."

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 SYNERGY Stent was previously referred to as the EVOLUTION Stent.

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 [2].

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, product performance and our market position. 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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