Boston Scientific

Boston Scientific Concludes Enrollment In Randomized, Multicenter, Pivotal Study Of SYNERGY™ Coronary Stent System

NATICK, Mass., Sept. 12, 2013 /PRNewswire/ -- In a significant milestone toward obtaining additional key regulatory approvals for the SYNERGY™ Stent System, Boston Scientific Corporation (NYSE: BSX) has completed enrollment in the EVOLVE II randomized, controlled clinical trial. The EVOLVE II trial is designed to further assess the safety and effectiveness of the SYNERGY Stent System and support U.S. Food and Drug Administration and Japanese regulatory approvals for the treatment of atherosclerotic coronary lesions. The SYNERGY stent uses the market-leading everolimus drug and features an ultra-thin directional polymer coating that is absorbed by the body shortly after drug elution ends at three months.

"The SYNERGY stent is the most flexible, conformable and deliverable drug eluting stent I have ever deployed," said Dean Kereiakes, M.D., F.A.C.C., The Christ Hospital Heart and Vascular Center, Cincinnati, Ohio and principal investigator for the study. "I am very pleased that the EVOLVE II trial enrolled so quickly and look forward to the study results for this innovative stent which was designed for optimal vessel healing."

The EVOLVE II trial began in November 2012 and has now completed enrollment of 1,684 patients at 125 sites worldwide, including the U.S., Canada, Europe, Australia, New Zealand, Japan and Singapore. Boston Scientific received CE Mark approval for the SYNERGY Stent System in October 2012.

The EVOLVE II clinical trial builds upon the EVOLVE study, which was a prospective, randomized, single-blind, first-in-human use study comparing the SYNERGY Stent System to the PROMUS Element™ Stent System, which uses a durable polymer coating. Two-year outcomes with the SYNERGY stent in EVOLVE were presented earlier this year at the EuroPCR Scientific Program in Paris and showed low rates of target lesion revascularization (1.1 percent) and no stent thrombosis with the SYNERGY stent throughout two years.

"Completing enrollment of EVOLVE II in just nine months is just one example of how Boston Scientific and the physician community are advancing cardiology together," said Kevin Ballinger, president, Interventional Cardiology, Boston Scientific. "The SYNERGY product underscores our ongoing commitment to delivering meaningful innovation to the interventional cardiology community and reinforces our position as a global leader in medical devices."

Patients enrolled in the EVOLVE II trial will be followed for five years. The SYNERGY Stent System is an investigational device in non-CE Mark countries and is not available for sale in the United States and Japan. To view or download an image of the SYNERGY Stent System, click here.

About Boston Scientific
Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 30 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com and connect on Twitter and Facebook.

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 our business plans, 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.

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