Boston Scientific

New Data Presented At EuroPCR 2015 Demonstrate Strong Performance Of The SYNERGY™ Bioabsorbable Polymer Stent System Over Four Years

Additional Data from EVOLVE II Pivotal Trial Demonstrate Safety and Performance in Patients with Diabetes at One Year

MARLBOROUGH, Mass., May 19, 2015 /PRNewswire/ -- Boston Scientific (NYSE: BSX) reported positive, long-term data from the EVOLVE Trial of the SYNERGY™ Everolimus-Eluting Bioabsorbable Polymer Platinum Chromium Coronary Stent System with no new major adverse cardiac events reported between years three and four. The study results were presented for the first time today at EuroPCR 2015 by Professor Ian Meredith, director of MonashHeart, at Monash Medical Centre in Melbourne, Australia.

Findings from year four of the EVOLVE Trial include the following key performance measures:

- the target lesion revascularization (TLR) rate was 1.1 percent compared to 6.1 percent for the PROMUS Element™ Plus Stent System (p=0.07); and
- no definite or probable stent thrombosis (ST) was observed.

"These long-term data from the EVOLVE Trial are quite important as they highlight the sustained safety and performance of the SYNERGY Stent," said Professor Meredith. "We continue to be encouraged by the consistently positive clinical data that point to the potential for improved healing with the SYNERGY Stent compared to durable polymer drug-eluting stents."

The EVOLVE Trial is the first human use, prospective, randomized, single-blind study evaluating the non-inferiority of the SYNERGY Stent, which employs an ultrathin bioabsorbable polymer coating applied to the abluminal (outer) surface of the stent. The comparator, the Boston Scientific PROMUS Element Plus Stent System, utilizes a durable polymer coating applied to the entire stent (inner and outer) surface. EVOLVE is the first in a continuing cadence of clinical trials evaluating the performance of the SYNERGY Stent in a range of patients.

In addition to these long-term data from the EVOLVE Trial, one-year findings from the EVOLVE II pivotal trial of 466 patients with diabetes treated with the SYNERGY Stent were presented today by Stephan Windecker M.D., chief of cardiology and head of invasive cardiology at the Swiss Cardiovascular Center in Bern, Switzerland. Patients with diabetes face an increased risk of heart disease, stroke and myocardial infarction.[1] The data presented for patients with diabetes include the following:

- the TLR rate was 4.4 percent; and
- definite/probable ST was 1.1 percent at one year, with no definite/probable ST events after the first week post percutaneous coronary intervention (PCI).

The EVOLVE II Trial includes a global, multi-center, randomized, single-blind, non-inferiority pivotal trial designed to evaluate the safety and performance of the SYNERGY Stent System compared to the durable polymer PROMUS Element Plus Stent System. The trial enrolled 1,684 patients in 125 sites worldwide. The EVOLVE II Trial is part of a rigorous clinical program designed to support the submission for U.S. Food and Drug Administration (FDA) and Japanese Ministry of Health, Labor and Welfare (MHLW) approval of the SYNERGY Stent.

The EVOLVE II Trial also includes a non-randomized, single-arm diabetes study. The EVOLVE II Diabetes Substudy pooled patients with diabetes randomized to the SYNERGY arm in the EVOLVE II pivotal trial with patients enrolled in the non-randomized single-arm diabetes study as pre-specified in the study protocol.

Patients in the EVOLVE II Trial demonstrated clinical and angiographic complexity to a degree not observed in prior U.S. pivotal trials for drug-eluting stents (DES). More than 25 percent of patients had non-ST elevation myocardial infarction (NSTEMI) and approximately 75 percent of patients had AHA/ACC class B2/C coronary lesions. As previously reported, EVOLVE II met its primary endpoint, demonstrating non-inferiority of SYNERGY versus the PROMUS Element Plus Stent for 12-month target lesion failure in the overall patient population.

"These long-term data, combined with the data for a particularly challenging group of patients—those with co-morbid diabetes—reinforce our belief in the difference the SYNERGY Bioabsorbable Polymer Stent can make for physicians and their patients," said Kevin Ballinger, president, Interventional Cardiology, Boston Scientific. "The SYNERGY Stent is designed to provide early healing and freedom from long-term polymer exposure, and we are confident that clinical studies and experience will continue to demonstrate excellent long-term outcomes."

About the SYNERGY Bioabsorbable Polymer Stent
If approved by the FDA, the SYNERGY Stent would become the first bioabsorbable polymer stent available to patients in the

U.S. It features ultrathin stent struts with an abluminal bioabsorbable drug/polymer coating technology that is absorbed shortly after drug elution is complete at three months, thereby eliminating long-term polymer exposure. Get more information on the SYNERGY Clinical Program and Research in the U.S. Information is also available for those outside the U.S.

The SYNERGY Stent is an investigational device in the U.S. and Japan, and is not available for sale in those countries. The SYNERGY Stent has CE mark approval and is available for sale in countries where CE mark is the regulation in force. View or download an image of the SYNERGY Stent.

About Coronary Artery Disease
Coronary artery disease is a narrowing of blood vessels that supply blood and oxygen to the heart. Patients with coronary artery disease may experience pain, shortness of breath and fatigue. They may also be at risk for a heart attack. One treatment option is the placement of a stent in the artery to help keep it open and allow the blood to flow more freely.

Diabetes and Heart Disease
People who have diabetes are twice as likely to have heart disease or a stroke, which typically occurs at younger age than in those who do not have diabetes. In addition, myocardial infarction in people with diabetes is more likely to result in death. Furthermore, persistent elevated blood glucose can result in an increase in fatty deposits that may affect blood flow, thereby increasing the risk of the development of atherosclerosis.[2]

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 35 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 new product launches and launch cadence, regulatory approvals, clinical trials and impact of data, product performance and impact 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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[1] National Diabetes Information Clearinghouse (NDIC). A service of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH); Accessed April 22, 2015.

[2] National Diabetes Information Clearinghouse (NDIC). A service of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH); Accessed April 22, 2015.

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