Boston Scientific

Clinical Data Reinforce Safety and Efficacy of Boston Scientific's Two Drug- Eluting Stent Platforms

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NATICK, Mass. and ORLANDO, Fla., March 29 /PRNewswire-FirstCall/ -- Boston Scientific Corporation today welcomed three-year results from the SPIRIT II Clinical Trial and a pooled meta-analysis of two-year data from the SPIRIT II and III Trials. SPIRIT II and SPIRIT III are prospective, randomized, non-inferiority trials with 300 and 1,002 patients respectively, designed to compare the safety and efficacy of the PROMUS® (XIENCE V™) Everolimus-Eluting Coronary Stent to Boston Scientific's first-generation TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent. SPIRIT II three-year results were presented by Patrick W. Serruys, M.D., Ph.D, and the two-year meta-analysis was presented by Yoshinobu Onuma, M.D., at the 58th Annual Scientific Session of the American College of Cardiology.

The two-year pooled meta-analysis was intended to estimate the incidence of low frequency events or outcomes in key subgroups, and included 892 patients randomized to the PROMUS (XIENCE V) Stent and 410 patients treated with the TAXUS Stent. While overall pooled results and some subgroups at two years favored the PROMUS (XIENCE V) Stent for rates of Major Adverse Cardiac Events (MACE), the MACE results in patients with diabetes favored the TAXUS Stent.

"Clinical data presented at ACC continue to reinforce the value of Boston Scientific's two-drug portfolio," said Keith D. Dawkins, M.D., Associate Chief Medical Officer of Boston Scientific. "While the PROMUS (XIENCE V) Stent performed well against the TAXUS Stent in the meta-analysis, it is important to note that 96 percent of the control patients received the TAXUS Express Stent, making the comparison almost entirely based on our first-generation technology. Of particular interest is the subgroup data on diabetics given the recent discussion in scientific journals regarding the difference between paclitaxel and other 'olimus stents in diabetic populations. Results from the TAXUS ATLAS trials with Boston Scientific's second-generation TAXUS Liberte® Stent yielded comparable efficacy and safety in diabetic and non-diabetic patients. These data were used to support the CE Mark approval of a diabetic indication for TAXUS Liberte in Europe."

Three-year data from the SPIRIT II Trial demonstrated that overall Major Adverse Cardiac Events (MACE), a composite endpoint, favored the PROMUS (XIENCE V) Stent compared to the TAXUS Stent (6.4% vs. 14.9% respectively, p=0.029), while the individual components of Myocardial Infarction (MI) and Ischemia-Driven Target Lesion Revascularization (ID-TLR) were not significantly different (MI: 3.3% vs. 6.8%, p=0.20; ID-TLR: 4.2% vs. 9.4%, p=0.092). The third MACE component, cardiac death, favored the PROMUS (XIENCE V) Stent (0.5% [n=1] vs. 4.2% [n=3], p=0.024). No corresponding difference in death was seen in the two-year data of the larger, subsequent SPIRIT III study (2.0% vs. 2.5%, p=0.59). Low and comparable rates of stent thrombosis were sustained at three years for PROMUS (XIENCE V) and TAXUS patients per the Academic Research Consortium (ARC) definite/probable definition (0.9% vs. 2.8%, p=0.27).

"We are pleased with the performance of our two key drug-eluting stents in these studies and with the continued progress in our pipeline," said Hank Kucheman, Senior Vice President and Group President, Cardiovascular for Boston Scientific. "Our second-generation TAXUS Liberte Stent launched earlier this month in Japan, and we look forward to introducing our third-generation Element™ Stent on both drug platforms. Patient enrollment in the PLATINUM clinical trial to evaluate the PROMUS Element Stent is ahead of plan, while the PERSEUS trial, designed to study the TAXUS Element Stent, has completed enrollment. Both Element™ stents are expected to be approved in Europe later this year."

The PROMUS Stent is a private-labeled XIENCE V Everolimus-Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific. XIENCE V is a trademark of Abbott Laboratories group of companies. The SPIRIT Clinical Program is sponsored by Abbott. The TAXUS Express Stent was the control in the SPIRIT III trial and both the TAXUS Express Stent (59 patients) and the TAXUS Liberte Stent (17 patients) were used as controls in the SPIRIT II trial.

The TAXUS Stent is not specifically indicated for use in patients with diabetes in the United States.

The TAXUS Element and PROMUS Element Stents are investigational devices and are limited by applicable law to investigational use only and are not available for sale in the United States.

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 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 and product performance. 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 thereafter. 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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