Boston Scientific Begins Platinum Plus Trial for Promus® Elementâ„¢ Stent System

Boston Scientific

NATICK, Mass., May 26 /PRNewswire-FirstCall [1]/ -- Boston Scientific Corporation (NYSE: BSX) today announced the initiation of the PLATINUM PLUS clinical trial, an investigator-sponsored research (ISR) study designed to compare the performance of the PROMUS® Element™ Everolimus-Eluting Coronary Stent System to the XIENCE PRIME™ Everolimus-Eluting Coronary Stent System. The PROMUS Element Stent, which received CE Mark in October 2009, is Boston Scientific's third-generation drug-eluting stent technology and incorporates a platinum chromium alloy with an innovative stent design and an advanced catheter delivery system.

PLATINUM PLUS is a prospective, randomized, multi-center clinical trial with planned enrollment of 2,980 patients at 50 sites in France, Germany, Italy, Spain and the U.K. It will evaluate coronary revascularization outcomes in an unrestricted patient population randomized (2:1) to receive a PROMUS Element Stent or XIENCE PRIME Stent. The primary endpoint is 12-month target vessel failure with planned follow-up out to 34 months. The trial is funded by a research grant from Boston Scientific and led by Principal Investigator Jean Fajadet, M.D., Clinic Pasteur, Toulouse, France and Co-Principal Investigator Eulogio Garcia, M.D., Clinico San Carlos, Madrid, Spain. Results are expected to be presented in 2012.

"We are very enthusiastic about beginning the first large-scale randomized trial that compares the new platinum chromium PROMUS Element Stent with the XIENCE PRIME Stent," said Dr. Fajadet. "The results should demonstrate how two distinct stent platforms, with the same everolimus drug, perform in a head-to-head comparison."

The PROMUS Element Stent is designed specifically for coronary stenting. The novel stent architecture and proprietary platinum chromium alloy combine to offer greater radial strength and flexibility. The stent architecture helps create consistent lesion coverage and drug distribution while improving deliverability, which is enhanced by an advanced catheter delivery system. The higher density alloy provides superior visibility and reduced recoil while permitting thinner struts compared to prior-generation stents(1).

The PLATINUM PLUS trial is coordinated by the Centre Europeen de Recherche Cardiovasculaire (CERC) under the direction of Marie-Claude Morice, M.D. CERC is an interventional cardiology clinical research organization based in Paris.

"This is an important study that could provide insights on the potential benefits of third-generation drug-eluting stents in an all-comers trial reflecting the daily clinical practice of interventional cardiologists," said Dr. Morice.

The PLATINUM PLUS trial will provide data that may complement Boston Scientific's PLATINUM clinical trial, which completed enrollment of 1,531 patients at 133 sites worldwide in September 2009. PLATINUM is a randomized, controlled, pivotal trial designed to support U.S. Food and Drug Administration (FDA) and Japanese Ministry of Health, Labor and Welfare (MHLW) approval of the PROMUS Element Stent System.

In addition to offering the PROMUS Element Everolimus-Eluting Coronary Stent System in the European Union and other CE Mark countries, the Company plans to launch the TAXUS® Element™ Paclitaxel-Eluting Coronary Stent System in these markets next month. Both Element Systems incorporate the same platinum chromium alloy, innovative stent design and advanced catheter delivery system. The Company expects FDA approval for the TAXUS Element Stent System in mid 2011 and for the PROMUS Element Stent System in mid 2012. It expects MHLW approval for the TAXUS Element Stent System in late 2011 or early 2012 and for the PROMUS Element Stent System in mid 2012.

In the U.S., the PROMUS Element and TAXUS Element Stent Systems are investigational devices and are limited by applicable law to investigational use only and are not available for sale.

XIENCE PRIME is a trademark of the Abbott Laboratories group of companies.

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.

(1) Based on bench testing. Data on file with Boston Scientific.

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