

Spirit III Clinical Trial Demonstrates Positive Performance for Both TAXUS® and PROMUS™ Drug-Eluting Stent Systems

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NATICK, Mass., and NEW ORLEANS, March 24 [PRNewswire-FirstCall/](#) -- Boston Scientific Corporation (NYSE: BSX) today welcomed the results of the pivotal SPIRIT III clinical trial, which reaffirmed prior safety and efficacy data for the market-leading TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System and provided early positive data for the XIENCE™ V (PROMUS™) Everolimus-Eluting Coronary Stent System. The XIENCE™ V Everolimus-Eluting Coronary Stent System is manufactured by Abbott and distributed on a private label basis by Boston Scientific as the PROMUS Everolimus-Eluting Coronary Stent System. Boston Scientific is the first company to offer two distinct drug-eluting stent platforms.

Results of the U.S.-based, non-inferiority trial were presented at the annual American College of Cardiology Scientific Session in New Orleans.

"This trial is important as it reinforces our understanding of the proven performance of the TAXUS Stent and generates enthusiasm for the early clinical data of this deliverable Olimus, the PROMUS Stent," said Martin B. Leon, M.D., of Columbia University Medical Center and the Cardiovascular Research Foundation, New York.

Gregg W. Stone, M.D., the trial's Principal Investigator, reported that the primary endpoint of angiographic in-segment late loss at eight months met its non-inferiority margin between the TAXUS Stent (0.28mm) and XIENCE V (PROMUS) Stent (0.14mm), $p_{NI} < 0.0001$. The TAXUS Stent results are consistent with data from previous trials in terms of low angiographic and clinical restenosis rates, with excellent safety results. The major clinical secondary endpoint of Target Vessel Failure (TVF, a composite of death, Myocardial Infarction, and ischemia-driven Target Vessel Revascularization at nine months) also showed non-inferiority between the TAXUS Stent (9.0%) and the XIENCE V (PROMUS) Stent (7.2%), $p_{NI} < 0.0001$, $P_{superiority} = 0.30$. Though not powered as an endpoint, ischemia-driven Target Lesion Revascularization (TLR, or re-treatment rate) was comparable between the TAXUS Stent (5.0%) and the XIENCE V (PROMUS) Stent (2.6%), $p = 0.053$. Target Vessel Revascularization (TVR) was also comparable between the TAXUS Stent (6.5%) and the XIENCE V (PROMUS) Stent (5.3%), $p = 0.47$.

The TAXUS Stent and XIENCE V (PROMUS) Stent demonstrated impressive safety results through nine months. In particular, the TAXUS Stent reported zero percent (0%) Stent Thrombosis and zero percent (0%) Q-Wave Myocardial Infarction (MI, or heart attack).

"In today's safety-conscious environment, it is reassuring to see both the TAXUS and PROMUS Stents performed exceptionally well in the SPIRIT III trial on multiple measures," said Hank Kucheman, Senior Vice President and Group President of Boston Scientific's Interventional Cardiology business. "We were particularly encouraged by the zero thrombosis and Q-wave MI rates for TAXUS."

Boston Scientific offers two highly deliverable and complementary drug-eluting stent technologies. The PROMUS Stent has CE Mark approval and is distributed in most European countries and other international markets. The PROMUS Stent is an investigational device in the U.S. and not yet approved for sale. It is currently under FDA review with an anticipated U.S. launch in 2008.

SPIRIT is sponsored by Abbott. TAXUS, Express2 and PROMUS are trademarks of Boston Scientific Corporation or its affiliates. XIENCE is a trademark of 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: <http://www.bostonscientific.com/>.

This press release contains forward-looking statements. Boston Scientific wishes to caution the reader of this press release that actual results may differ from those discussed in the forward-looking statements and may be adversely affected by, among other things, risks associated with product development and commercialization, clinical trials, intellectual property, regulatory approvals, competitive offerings, integration of acquired companies, Boston Scientific's overall business strategy, and other factors described in Boston Scientific's filings with the Securities and Exchange Commission.

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