# ACC Data Show Numerical Trend Favoring TAXUS® Coronary Stent System Diabetics and other complex patients see strong results with TAXUS stents

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NATICK, Mass., March 29 /<u>PRNewswire-FirstCall</u>/ -- Boston Scientific Corporation (NYSE: BSX) welcomed recent results from studies presented at the annual American College of Cardiology Scientific Session in Atlanta, March 11- 14. Several clinical trials and registries offered data that indicated a positive numerical trend in the performance of the TAXUS® Express2<sup>™</sup> paclitaxel-eluting stent system when used in complex patients. Studies ranged from larger, real-world registries to smaller clinical trials and compared the TAXUS Express2 stent system to bare-metal stent control groups and to competitive drug-eluting stent systems.

"Information presented at ACC provides continuing evidence that the TAXUS stent shows positive results in complex patients," said Hank Kucheman, President of Boston Scientific's Interventional Cardiology business. "The combination of superior deliverability and proven, positive outcomes across a broad range of patients illustrates why in virtually every market where we do business, TAXUS remains the drug-eluting stent of choice."

## STENT REGISTRY DIABETIC DATA

The STENT Registry showed nine-month results from 5,566 patients at eight coronary centers in the United States who received either a TAXUS Express2 paclitaxel-eluting coronary stent system or a Cypher® stent system. The registry included 1,680 diabetic patients, nearly 500 of whom were insulin- treated diabetics. Among insulin-treated diabetics, the results demonstrated a numerical trend toward improved survival and lower overall Major Adverse Cardiac Events (MACE) rate for patients who received a TAXUS stent system versus those who received a Cypher stent system. In the less complex non- insulin treated diabetic population, the stents showed equal performance.

Among the study's diabetic patients, the TAXUS stent system was used in more complex lesions than Cypher. The TAXUS patients had a slightly higher ACC risk score, smaller vessels and longer lesions than Cypher patients. Despite the higher complexity of the TAXUS patients, the results favored the TAXUS stent system over the Cypher stent system in each of the study's MACE categories for insulin-treated diabetics. In these patients, the MACE rate was a composite of death (2.1 percent for TAXUS versus 5.7 percent for Cypher), myocardial infarction (MI, or heart attack) (1.3 percent for TAXUS versus 1.9 percent for Cypher), and target vessel revascularization (TVR) (3.4 percent for TAXUS versus 4.2 percent for Cypher). The overall MACE rate in these patients also trended in favor of TAXUS (6.0 percent versus 10.7 percent for Cypher).

## REWARD REGISTRIES

In a study of 3,115 consecutive diabetic patients, Ron Waksman, M.D., Associate Director, Division of Cardiology, Washington Hospital Center and the Director of Experimental Angioplasty and Vascular Brachytherapy for the Cardiovascular Research Institute at the Washington Hospital Center, Washington, D.C., concluded that treating these patients with either a sirolimus-eluting stent (Cypher) or a paclitaxel-eluting stent (TAXUS) was associated with similar six-month outcomes, regardless of insulin therapy. Patients in the TAXUS group had undergone more previous percutaneous coronary interventions (PCI), experienced more prior acute myocardial infarctions and/or had more complex, ACC/AHA Type C lesions. While there was no significant difference in the study's primary endpoint of TVR/MACE, the study did find a statistically significant difference in the rate of stent thrombosis between the two stents. The overall stent thrombosis rate in the TAXUS group was 0.6 percent, compared to 1.5 percent in the Cypher group (P=0.03).

## ARRIVE II REGISTRY

ARRIVE II studied more than 5,000 consecutively enrolled patients across 53 sites in the U.S., including patients with complex lesions (65 percent), multiple stents (38 percent) and diabetes (32 percent). The diabetic sub-population analysis demonstrated positive results, showing an overall TAXUS- related major cardiac event rate of 3.3 percent and a re-intervention rate of 1.9 percent.

#### TAXUS IV, V AND VI META-ANALYSES

In a meta-analysis of TAXUS IV, V and VI incorporating intravascular ultrasound data from 730 patients, Neil J. Weissman, M.D., director of the Cardiac Ultrasound and Ultrasound Core Laboratories at the Cardiovascular Research Institute at Washington Hospital Center and associate professor of medicine at Georgetown University School of Medicine in Washington, D.C., concluded that "treatment with the TAXUS stent neutralizes the impact of diabetes on tissue regrowth and restenosis." Weissman cites a rate of 11.6 percent tissue re-growth in patients who do not have diabetes and have received a TAXUS stent, compared to an equivalent rate of 13.7 percent in patients who do have diabetes. The amount of tissue regrowth in diabetic patients treated with the TAXUS stent was also markedly less than diabetic patients treated with bare-metal stents (13.7 percent versus 34.6 percent).

In a separate meta-analysis of TAXUS IV and V consisting of 674 patients, the trial's Principal Investigator, Gregg W. Stone, M.D., Professor of Medicine, Columbia University Medical Center in New York, reported that small reference vessel diameter and long lesion length remain strong predictors of clinical and angiographic restenosis after implantation of a paclitaxel- eluting stent. However, treatment with a TAXUS stent significantly reduced the impact of diabetes on restenosis. Among diabetics, the target lesion revascularization (TLR) rate with a bare-metal stent at one year was 20.4 percent, compared to 9.2 percent with the TAXUS stent.

### STRONG PERFORMANCE IN IN-STENT RESTENOSIS

TAXUS V ISR(1) is a prospective, randomized, open-label, controlled study of 396 patients at 37 sites in the United States designed to assess the TAXUS stent slow-release formulation paclitaxel-eluting coronary stent system in reducing in-stent restenosis (the re-growth of diseased tissue into a previously stented artery) versus intracoronary brachytherapy (radiation delivered directly to the lesion). The study met its primary endpoint of improved nine-month target vessel revascularization (TVR), which was significantly lower in the TAXUS stent group (10.5 percent), as compared to the control group (17.5 percent). The study demonstrated a nine-month target lesion revascularization (TLR) rate of 6.3 percent in the TAXUS stent group, as compared to 13.9 for the control group. The study demonstrated an 11.5 percent MACE rate for the TAXUS stent group, as compared to 20.1 percent rate for the control group. Of note, 40 percent of the patients in the TAXUS stent group were diabetics versus 30.3 percent in the control group (p=0.04).

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: <u>http://www.bostonscientific.com/</u>.

CONTACT: Milan Kofol 508-650-8569 Investor Relations Boston Scientific Corporation

> Paul Donovan 508-650-8541 Media Relations Boston Scientific Corporation

#### Forward-Looking Statements

This press release contains "forward-looking statements," including, among other statements, statements regarding the proposed business combination between Boston Scientific Corporation and Guidant Corporation, and the anticipated consequences and benefits of such transaction. Statements made in the future tense, and words such as "anticipate", "expect", "project", "believe", "plan", "estimate", "intend", "will", "may" and similar expressions are intended to identify forward-looking statements. These statements are based on current expectations, but are subject to certain risks and uncertainties, many of which are difficult to predict and are beyond the control of Boston Scientific or Guidant. Relevant risks and uncertainties include those referenced in Boston Scientific's and Guidant's filings with the Securities and Exchange Commission ("SEC") (which can be obtained as described in "Additional Information" below), and include: general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; and trends toward health care cost containment. Risks and uncertainties relating to the proposed transaction include: required regulatory approvals will not be obtained in a timely manner, if at all; the proposed transaction will not be consummated; the anticipated benefits of the proposed transaction will not be realized; and the integration of Guidant's operations with Boston Scientific will be materially delayed or will be more costly or difficult than expected. These risks and uncertainties could cause actual results to differ materially from those expressed in or implied by the forward-looking statements, and therefore should be carefully considered. Neither Boston Scientific nor Guidant assumes any obligation to update any forward-looking statements as a result of new information or future events or developments.

#### Additional Information

Boston Scientific and Guidant have filed a definitive prospectus/joint proxy statement with the SEC in

connection with the proposed transaction. The material contained herein is not a substitute for the definitive prospectus/joint proxy statement or any other documents that Boston Scientific and Guidant have filed or will file with the SEC. Investors and security holders are urged to read the definitive prospectus/joint proxy statement and any other relevant documents filed or to be filed by Boston Scientific or Guidant, because they contain or will contain important information about the proposed transaction. The definitive prospectus/joint proxy statement is, and other documents filed or to be filed by Boston Scientific and Guidant with the SEC are or will be, available free of charge at the SEC's website (http://www.sec.gov/) or from Boston Scientific by directing a request to Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, Attention: Milan Kofol, Investor Relations, or from Guidant by directing a request to Guidant Corporation, 111 Monument Circle, 29th Floor, Indianapolis, Indiana 46204, Attention: Investor Relations.

Boston Scientific, Guidant and their respective directors, executive officers and other employees may be deemed to be participants in the solicitation of proxies from the security holders of Boston Scientific or Guidant in connection with the proposed transaction. Information about Boston Scientific's directors and executive officers is available in Boston Scientific's Annual Report on Form 10-K for the year ended December 31, 2005, and information about Guidant's directors and executive officers is available in Guidant's directors and executive officers is available in Guidant's Annual Report on Form 10-K for the year ended December 31, 2005. Additional information about the interests of potential participants is included in the definitive prospectus/joint proxy statement referred to above.

(1) CAUTION -- The TAXUS(r) Express2<sup>™</sup> paclitaxel-eluting stent system is considered investigational in the United States for use in treating in- stent restenosis and for this indication is limited by Federal Law to investigational use only.

SOURCE: Boston Scientific Corporation

CONTACT: Milan Kofol, Investor Relations, +1-508-650-8569, or Paul Donovan, Media Relations, +1-508-650-8541, both of Boston Scientific Corporation

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