Boston Scientific

Data Presented To FDA Panel Show TAXUS Drug-Eluting Stents as Safe as Bare-Metal Stents and Far More Effective in Reducing Repeat Procedures

NATICK, Mass. and GAITHERSBURG, Md., Dec. 7 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today presented data on its long- term randomized clinical trials to a special U.S. Food and Drug Administration (FDA) panel, showing that the TAXUS® paclitaxel-eluting coronary stent is as safe as bare-metal stents and far more effective in keeping arteries open and reducing the need for repeat procedures.

The data were presented by Dr. Donald S. Baim, Chief Medical and Scientific Officer for Boston Scientific, during the first day of a two-day hearing before a panel of experts assembled by the FDA in response to concerns about the incidence of late stent thrombosis, or blood clots, in drug-eluting stents.

The Boston Scientific data presented by Dr. Baim were based on a detailed analysis of 2,797 patients who received TAXUS or bare-metal stents for approved indications and were followed closely for four years. The data showed that the TAXUS stent reduced the need to for repeat procedures due to restenosis by nearly 50 percent compared to bare-metal stents. Restenosis is a condition in which vessels cleared of blockages develop scar tissue and close again after a stenting procedure.

Data presented at the October Transcatheter Cardiovascular Therapeutics (TCT) meeting showed a small but statistically significant increase in very late stent thrombosis in clinical trials studying 3,445 patients treated with either the commercial (slow-release formulation) or an investigational (moderate-release formulation) TAXUS stent compared to bare-metal stents. However, the data requested by the FDA and presented today included only the 2,797 patients in TAXUS trials studying the commercialized (slow-release formulation) TAXUS stent. The very late stent thrombosis rate for this group was not statistically different from the bare-metal stent control group, according to any of the available definitions. Moreover, there was no evidence of an increase in clinical complications in the TAXUS stent group, and favorable risk-benefit outcomes were seen in important trial subgroups, including patients with diabetes, small vessels and multiple stents per vessel.

"When used for approved indications, the TAXUS stent is twice as effective as bare-metal stents in keeping vessels open, helping patients stay healthy and avoid restenosis and the need for repeat procedures," said Dr. Baim. "It is important to understand that restenosis is not benign. The benefits of the TAXUS stent in reducing restenosis-related deaths and heart attacks offset the small (but not statistically significant) clotting events that led to deaths or heart attacks. Overall, the total number of deaths in the TAXUS stent group was the same or slightly lower than the bare-metal stent group throughout the four years following the procedure."

"We have continued to be forthcoming and transparent with the clinical data related to our drug-eluting stents because we believe it is important to help doctors and patients make the best and most informed decisions," said Dr. Baim.

In his presentation to the panel, Dr. Baim reviewed four randomized TAXUS clinical trials that compared the TAXUS stent to bare-metal stents in 2,797 patients for four years. The detailed analysis of this data showed that under any and all definitions proposed to define late stent thrombosis, there was no statistically significant increase in stent thrombosis with the TAXUS stent. The analysis also showed that the low rates of death and heart attacks were essentially the same or lower for the TAXUS stent compared to bare-metal stents.

Dr. Baim said the risk of stent thrombosis is greatest in the first year following implantation, and drops off to very low levels thereafter for both bare-metal and drug-coated stents, a finding corroborated by other studies. Boston Scientific is continuing to study stent thrombosis and has agreed to provide lead financial support for an extension of the independent STENT registry, which will include the enrollment of an additional 10,000 drug- eluting stent patients.

Dr. Baim also presented data indicating that patients have a far better chance of avoiding blood clots if they take anti-clotting drugs for six or more months after a stenting procedure. The data is consistent with current published recommendations from the American Heart Association and American College of Cardiology Guidelines for Percutaneous Coronary Intervention that advocate that patients with drug-coated stents who are tolerating these medications well may benefit from continuing to take them for a year or more, although the current TAXUS label recommends only six months of such therapy. The adoption of longer anti-clotting drug therapy after drug-coated stents is one of the topics the FDA panel is expected to consider at the conclusion of testimony on Friday.

"Given our extensive review of the clinical data, Boston Scientific remains confident in the safety and efficacy of the TAXUS stent in the types of patients studied in the TAXUS trials," said Dr. Baim. "The company hopes its detailed presentation to the FDA panel will help clarify these issues and reduce concerns raised about very late stent thrombosis by putting the benefits and risks of this important therapy in perspective."

Before joining Boston Scientific earlier this year, Dr. Baim was a professor of medicine at Harvard Medical School, founder and chief of the Interventional Cardiology section at the Beth Israel Deaconess Medical Center, a senior physician at the Brigham and Women's Hospital and co-founder of the Harvard Clinical Research Institute.

Stents are tiny wire-mesh devices used to keep arteries open after they have been cleared of plaque by balloon angioplasty. Drug-eluting stents represent the most advanced stenting technology and work by releasing a drug after they are inserted that is designed to prevent a vessel from renarrowing during the healing process.

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 new product development and commercialization, clinical trials, intellectual property, regulatory approvals, competitive offerings, 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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