Boston Scientific

Real-World Taxus® Stent Data Confirm Favorable Outcomes for Patients With Complex Coronary Artery Disease

NATICK, Mass. and GAITHERSBURG, Md., Dec. 7 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today presented data on its 7,000- patient ARRIVE I and II registries of real-world patients -- including those with complex lesions -- to a special U.S. Food and Drug Administration (FDA) panel. The data showed that the TAXUS® paclitaxel-eluting coronary stent provides substantial benefits in keeping arteries open and avoiding repeat procedures for patients with complex coronary artery disease, at no higher risk than alternative cardiovascular treatments.

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

Dr. Baim first appeared before the panel on Thursday morning, when he outlined data on Boston Scientific's long-term randomized clinical trials in 2,797 patients with somewhat less complex lesions. The data showed that the TAXUS stent is as safe as bare-metal stents and far more effective in reducing the need for repeat procedures.

While these TAXUS randomized clinical trials focused on patients who received a single stent to relieve blockage in a single vessel, the patients enrolled in the ARRIVE registries tended to present much more complex situations involving very small, very long or multiple vessel blockages that often required multiple stents. These patients represent up to two-thirds of the patients who receive TAXUS stents in the real-world practice of interventional cardiologists.

The data presented by Dr. Baim showed that patients in the ARRIVE registries with simple blockages had comparable outcomes to those with similar lesions in the TAXUS clinical trials, confirming the ability of these registries to accurately track clinical outcomes. As expected, patients with complex coronary artery disease had slightly higher adverse events compared to the randomized trials and the simpler cases in the ARRIVE registries. However, the rates of death and heart attack were equivalent or better than those for potential alternative treatments such as bypass surgery. The data on complex cases were also consistent with other real-world registries of drug-eluting stents using either the TAXUS or CYPHER® stent. These registries showed trends towards lower rates of death, heart attack, and repeat procedures for TAXUS stents compared to CYPHER stents, in patients with diabetes mellitus.

"The patients treated in ARRIVE had such complex disease that many would have been poor candidates for bare-metal stents or conventional angioplasty," said Dr. Baim. "They were just too sick and the standard treatment for many of these patients would have been bypass surgery, yet the patients treated with the TAXUS stent had similar or lower rates of death, heart attacks and repeat procedures than historically seen with bypass surgery."

"What the ARRIVE data show is that in complex, real-world cases, TAXUS stents provided the benefits of keeping vessels open and reducing the need for repeat procedures, with rates of adverse events that were no worse, and in many cases better, than other alternative treatments, including bypass surgery," said Dr. Baim.

Dr. Baim added that pending the results of randomized studies of even more complex cases, "there is no reason to believe that current clinical use exposes complex patients to excess risk compared to other available revascularization therapies."

The FDA panel, which will conclude two days of hearings on Friday, first considered data involving approved uses of drug-eluting stents before moving to uses by interventional cardiologists for other kinds of cases, many of them involving complex heart disease or subsets like diabetic patients.

In his earlier 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 followed for four years. The detailed analysis of those data shows that under any and all definitions proposed for very 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. Moreover, the TAXUS stent demonstrated a profound clinical benefit, with a sustained reduction of nearly 50 percent in repeat procedures compared to bare-metal stents. These favorable risk-benefit outcomes were seen in important trial subgroups, including patients with diabetes, small vessels and multiple stents per vessel.

Enrollment is approaching completion in two additional landmark randomized trials comparing the TAXUS stent to bare-metal stents in patients with acute heart attacks and comparing the TAXUS stent to bypass surgery in the most complex patients with narrowing of the left main coronary artery and/or narrowing of all three coronary arteries.

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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