Boston Scientific

ARRIVE Registry Analysis Identifies Predictors of Stent Thrombosis in Real-World Use of Drug-Eluting Stents

NATICK, Mass. and BARCELONA, Spain, May 22 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced results from an analysis of more than 7,000 patients from its ARRIVE 1 and 2 registries, designed to assess the performance of the TAXUS® Express2™ paclitaxel- eluting coronary stent system in "real-world" practice. The objective of the analysis was to identify baseline predictors of stent thrombosis (blood clots) at one and two years post-implant to better guide physician recommendations for patient therapy following treatment with drug-eluting stents. Analysis of the data was presented by David Dobies, M.D., F.A.C.C., at the annual Paris Course on Revascularization (EuroPCR) in Barcelona.

The analysis included two-year data on 2,487 patients from ARRIVE 1 and one-year data on a pooled group of 7,307 patients from ARRIVE 1 and 2. More than 30 baseline characteristics were assessed as predictors of stent thrombosis at various time periods up to two years using the ARC (Academic Research Consortium) definition of "definite plus probable, total." Stent thrombosis is a rare but serious adverse event that can occur with both bare- metal and drug-eluting stents (DES) at any time following stent implantation but often occurs within the first 30 days. Risk factors associated with DES stent thrombosis include acute coronary syndrome, stent length, stent underexpansion and non-compliance with antiplatelet therapy. Predictive analyses for stent thrombosis can be limited by low event numbers, however, the size of the ARRIVE program allowed identification of low-frequency TAXUS stent-related clinical events.

Patients in the study were prescribed antiplatelet therapy in accordance with the TAXUS Stent label, including indefinite aspirin therapy and six months of clopidogrel or ticlopidine. At one year, 92.8 percent of patients remained on aspirin while 71.5 percent continued with antiplatelet therapy. At two years (ARRIVE 1 patients only), 92.2 percent were on aspirin and 58.5 percent remained on antiplatelet therapy. Rates of stent thrombosis in the pooled patient set were 1.0 percent from 0-30 days, 0.3 percent from 31-180 days, and 0.4 percent from six months to one year. Stent thrombosis for ARRIVE 1 patients from one to two years (very late stent thrombosis or VLST) was 0.7 percent. These rates are similar to findings of previous studies and align well with patient and lesion risk profiles.

The analysis showed that discontinuation of antiplatelet therapy before six months is a significant predictor of stent thrombosis at both one and two years. Information available from 13 of 16 VLST patients showed that 30.8 percent of these patients had discontinued dual antiplatelet therapy within seven days of a VLST event. Other statistically significant predictors of stent thrombosis up to one year include several lesion characteristics, including long lesions, multiple stents, calcified lesions and small vessels, as well as patient-related factors such as smoking and congestive heart failure. Significant stent thrombosis predictors from one to two years consist of more biologic factors, including failed brachytherapy, chronic total occlusions, prior myocardial infarction and age.

"The ARRIVE data indicate that antiplatelet therapy is an important factor relating to the occurrence of stent thrombosis in DES patients," said Dr. Dobies, Director, Genesys Heart Institute, Grand Blanc, Michigan. "Other significant predictors change from one to two years, suggesting differences in pathophysiology that may require additional study."

"Our extensive ARRIVE registries provide valuable insight into the key predictors for stent thrombosis in real-world DES use," said Paul LaViolette, Chief Operating Officer of Boston Scientific. "Determination of baseline predictors may help identify patients at highest risk for stent thrombosis. At a minimum, these data reinforce the need for post-implant antiplatelet compliance. Physicians should emphasize to their patients the importance of strict adherence to prescribed antiplatelet therapy and physicians should also consider any new information from the clinical guidelines or the FDA as it becomes available."

ESC and AHA/ACC guidelines recommend a daily anti-platelet regimen for at least one month after bare-metal stent implantation, and six months after TAXUS drug-eluting stent implantation, and ideally up to 12 months in patients who are not at high risk of bleeding. The TAXUS Express Stent Directions For Use (DFU) recommends six months of dual antiplatelet therapy.

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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