Boston Scientific

Boston Scientific Announces Results from TAXUS Registries

and Washington, D.C. (October 1, 2004) -- Boston Scientific Corporation (NYSE: BSX) today announced data supporting safety from three post-market registries associated with its TAXUS™ Express^2™ paclitaxel-eluting coronary stent system. A registry program enlists clinicians to document the performance of a specific therapy for a particular disease or condition. In total, these registries studied more than 7,000 patients at 236 sites around the globe. The results were consistent with controlled TAXUS studies. The Company made the announcement at the annual Transcatheter Cardiovascular Therapeutics symposium in Washington, D.C.

"Our TAXUS registries are providing invaluable 'real-world' data from nearly every corner of the globe and further demonstrate that the TAXUS stent system is safe in the treatment of coronary artery disease," said Jim Tobin, President and Chief Executive Officer of Boston Scientific. "These results are particularly impressive given the wide-range of patients, practices and clinical settings that were included in these studies."

ARRIVE

The ARRIVE peri-approval registry has enrolled nearly 2,600 consecutive patients at 50 sites in the United States. (A peri-approval registry includes patients who are enrolled before and after a product is approved.) ARRIVE was initiated in cooperation with the U.S. Food and Drug Administration (FDA) and is the first TAXUS registry in the United States. The Company today announced that results from ARRIVE demonstrated safety based on a site-reported 30-day adverse event rate of 2.7 percent (70/2,582), including site-reported cardiac death, myocardial infarction and reintervention of the target vessel. The registry reported a stent thrombosis rate of 1.3 percent (angiographically confirmed thrombotic events and all deaths less than 30 days without obvious cause). ARRIVE reported a 99 percent follow-up at 30 days.

ARRIVE has demonstrated that consecutive enrollment yields a very diverse patient population involving patients receiving multi-vessel stenting (17 percent), left main stenting (3.0 percent), stenting of chronic total occlusions (2.0 percent), stenting of bifurcated lesions (8.0 percent), stenting of saphenous vein grafts (6.0 percent) and stenting of in-stent restenonic lesions (7.0 percent).

"The results from ARRIVE represent another important development in the evolution of the TAXUS stent system and are consistent with safety data we have seen across other TAXUS registries," said John Lasala, M.D., Ph.D., of Barnes-Jewish Hospital and Washington School of Medicine in St. Louis and Co-Principal Investigator of ARRIVE. "By enrolling consecutive patients, we are able to see how the TAXUS stent performs in a wide-range of complex cases that represent what physicians face on a day-to-day basis."

MILESTONE II

The Milestone II registry was designed as a follow-up to the Milestone I registry (which evaluated usage patterns of the Express^2™ bare metal stent system) to assess the TAXUS paclitaxel-eluting stent system. On a global basis, the registry has enrolled 3,688 patients at 164 centers in 32 countries. The Company today announced six-month global data from Milestone II that supports safety and demonstrates that physicians are using the TAXUS stent system to treat difficult lesions and cases, particularly in diabetic patients. Milestone II reported a 96 percent follow-up at six months. Boston Scientific reported a 4.9 percent Cardiac Adverse Event rate (cardiac death, myocardial infarction, need for repeat procedures), a rate of 2.8 percent for repeat procedures and a 1.2 percent reported stent thrombosis rate per patient (angiographically confirmed thrombotic events and all deaths less than 30 days without obvious cause). For the overall diabetic population, which was 33.9 percent of the Milestone II patient population, the Cardiac Adverse Event rate was 6.0 percent and the need for repeat procedures was 3.6 percent.

"With Milestone II, we've set a new standard for drug-eluting stent registries in how rigorously we've examined this data," said Kari Niemela, M.D., Milestone II's Principal Investigator and Director of the Heart Center at University Hospital, Tampere, Finland. "As a result, the data, which is derived from a large and diverse patient population, is even more compelling and provides further substantiation of the important impact TAXUS is having on patients suffering from coronary artery disease."

WISDOM

The WISDOM transitional registry was initiated in 2002 as part of a limited commercial launch of the Company's TAXUS stent system, to assess the usage patterns of the first TAXUS slow-release formulation. As an international, multi-center, prospective, observational registry, WISDOM is collecting and analyzing data on 778 patients in nine countries. The Company today announced one-year results for WISDOM that demonstrated safety based on site-reported clinical outcomes. The WISDOM database reports a 92 percent follow-up at 12 months with a population that is 33 percent diabetic. In the overall WISDOM patient population, the study reported a 5.2 percent Cardiac Adverse Event rate (cardiac death, myocardial infarction, need for reinterventions), a rate of 2.0 percent for reinterventions and a 0.6 percent reported stent thrombosis rate (acute and late angiographically confirmed thrombotic events).

"We are very enthusiastic about the data we are receiving from the WISDOM registry," said Alexandre Abizaid, M.D., Ph.D., Principal Investigator for WISDOM and Director of Coronary Interventions at the Instituto Dante Pazzanese de Cardiologia Sao Paulo, Brazil. "The results at 12 months post-intervention demonstrate an excellent safety profile for the TAXUS stent in this patient population, many of whom were high-risk. The data is extremely impressive and represents a significant achievement for the TAXUS program."

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: www.bostonscientific.com.

This press release contains forward-looking statements. The Company 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 clinical trials, the regulatory approval process, commercialization of new technologies, third party intellectual property and other factors described in the Company's filings with the Securities and Exchange Commission.

---

https://news.bostonscientific.com/news-releases?item=58799