THE 2.25 MILLIMETER XIENCE V® EVEROLIMUS ELUTING CORONARY STENT SYSTEM FOR THE TREATMENT OF SMALL CORONARY ARTERIES: THE SPIRIT SMALL VESSEL TRIAL

i2 Poster Contributions
Ernest N. Morial Convention Center, Hall F
Sunday, April 03, 2011, 10:00 a.m.-11:15 a.m.

Session Title: PCI - DES I
Abstract Category: 16. PCI - DES (clinical/outcomes)
Session-Poster Board Number: 2501-512

Authors: Marco A. Costa, Jennifer Jones, F. James Fleischhauer, Wai-Fung Cheong, Hajime Kusano, Naim Farhat, Jin Wang, William Lombardi, Zhen Zhang, James Maddux, David Megio, Xiaolin Li, Louis Cannon, Kyoko Hattori, Malcolm T. Foster, III, Poornima Sood, Daniel Simon, Harrington-McLaughlin Heart and Vascular Institute University Hospitals, Case Western Reserve, Cleveland, OH, Abbott Vascular, Santa Clara, CA

Background: Subjects with small coronary arteries have a higher rate of restenosis and clinical events after percutaneous coronary intervention compared to those with larger vessels. The commercial XIENCE V everolimus eluting coronary stent system (EECSS) is associated with low rates of restenosis and thrombosis in the general population, but the 2.25 millimeter (mm) XIENCE V has not been tested in the United States. The SPIRIT Small Vessel (SV) is the Food and Drug Administration approval trial to determine the safety and effectiveness of the 2.25 mm XIENCE V EECSS in subjects with small vessels and ischemic heart disease.

Methods: This prospective, single-arm, open-label study was conducted at 33 centers in United States. Consecutive patients with a maximum of two de novo native coronary artery lesions ≤ 28 mm in length and in vessels ≥ 2.25 mm to < 2.5 mm in diameter were enrolled. The primary endpoint was the target lesion failure (TLF) rate at 1-year, required to meet the pre-specified performance goal of 20.4%, based on historical data.

Results: Of the 150 subjects enrolled, 144 subjects received at least one 2.25 mm XIENCE V stent and 69 subjects were included in the 240 day angiographic cohort. Enrollment was completed on November 4, 2009. The mean age was 62.97±10.59 years, 61.8% (89/144) of the population was male and 39.2% (56/143) were diabetic. The mean reference vessel diameter was 2.13±0.23 mm, 72.2% (104/144) of subjects had one vessel treated and 27.8% (40/144) had two vessels treated. Interim analysis at 268 days (240±28 days) revealed 0.16±0.41 mm in-segment and 0.2±0.4 mm in-stent late loss and 9.6% (5/52) in-segment and 3.8% (2/52) in-stent binary restenosis rates. The TLF rate was 7.2% (10/139), the cardiac death rate was 1.4% (2/139), the target vessel myocardial infarction rate was 1.4% (2/139) and clinically indicated target lesion revascularization rate was 4.3% (6/139). The 268 day academic research consortium defined definite/probable stent thrombosis rate was 1.4% (2/139).

Conclusion: Based on this interim analysis, the 2.25 mm XIENCE V EECSS appears safe and effective through 268 days. Primary endpoint data through 1 year will be available at the time of the presentation.