Primary Outcomes of the EVOLVE II Trial: A Prospective Randomized Investigation of a Novel Bioabsorbable Polymer-Coated, Everolimus-Eluting Coronary Stent

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Introduction: Durable polymers have been associated with hypersensitivity, delayed healing and incomplete endothelialization which may contribute to increased risk of late/very late stent thrombosis and the need for prolonged dual antiplatelet therapy. The SYNERGY stent (Boston Scientific Corporation, Natick, MA) consists of a thin-strut, platinum chromium metal alloy platform and an ultrathin bioabsorbable poly(DL-lactide-co-glycolide) abluminal polymer which elutes everolimus. Drug release and polymer absorption are complete within 4 months. The SYNERGY metal platform was designed specifically to improve flexibility, radiopacity, radial strength, and fracture resistance compared to previous stents. We compared the SYNERGY everolimus-eluting stent (EES) to the durable polymer PROMUS Element EES in a large-scale, multicenter, multinational, prospective, single-blind randomized controlled pivotal trial for regulatory approvals.

Methods: Patients with up to 3 native coronary artery lesions in up to 2 major epicardial vessels undergoing PCI were considered for enrollment. Lesion inclusion criteria included reference vessel diameter (RVD) =2.25 mm to =4.00 mm, and length =34 mm. Exclusion criteria included STEMI and complex lesion morphology, including left main or ostial location, major bifurcation disease, chronic total occlusion, vein grafts, thrombus or 3 vessel disease. Eligible patients were randomized 1:1 to SYNERGY or PROMUS Element. The primary endpoint is target lesion failure (composite occurrence of ischemia-driven target lesion revascularization, target vessel related MI, or cardiac death) to 12 months.

Results: Between November 2012 and August 2013, 1684 patients were enrolled and randomized at 125 sites in North America, Europe, Australia, New Zealand, Japan, and Singapore. Mean patient age was 63.7 years, 28.4% were women, 30.9% had
medically-treated diabetes and 34.3% presented with unstable angina. Mean RVD was 2.63 mm; mean lesion length was 13.9 mm.

**Conclusions:** Enrollment in the EVOLVE II pivotal trial for evaluation of the novel bioabsorbable polymer SYNERGY EES, has been completed. The primary endpoint and major secondary endpoint results through 12 months will be available for presentation at AHA 2014.

Disclosures: