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THREE-YEAR RESULTS FROM THE EVOLVE II RANDOMIZED TRIAL: LATE CLINICAL OUTCOMES WITH BIORESORBABLE COMPARED TO PERMANENT POLYMER EVEROLIMUS-ELUTING

Moderated Poster Contributions
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Background: Although drug-eluting stents reduce cardiac events compared with bare metal stents, permanent polymers may result in chronic inflammation, delayed arterial healing and increased risk of late cardiac events. Resorbable polymers may reduce inflammation and mitigate late/ very-late adverse outcomes. SYNERGY (Boston Scientific Corporation, Marlborough, MA) is a thin-strut platinum chromium metal alloy coronary stent with an ultrathin abluminal bioresorbable polymer [poly(DL-lactide-co-glycolide)] which fully absorbs early after drug elution (_3 months). EVOLVE II demonstrated comparable efficacy and safety of SYNERGY compared to PROMUS Element Plus (PE+) through 2-years with a relative reduction in stent thrombosis (ST) beyond 24 hours (HR [95% CI] 0.16 [0.02, 1.37], p=0.056). The impact of polymer type over longer-term follow-up is unknown.

Methods: Patients (n= 1684) with ≤3 native coronary artery lesions (RVD ≥2.25 - ≤4.00 mm; length ≤34 mm) in ≤2 major vessels were randomized 1:1 to SYNERGY or the durable polymer PROMUS Element Plus stent (PE+). The primary endpoint was target lesion failure (TLF: ischemia-driven target lesion revascularization [TLR], target vessel related myocardial infarction [MI], or cardiac death) at 12 months.

Results: Mean patient age was 64 years, 28% were women, >60% had acute coronary syndromes, >25% MI, 31% diabetes, and ≥75% B2/C lesion morphology. SYNERGY was non-inferior to PE+ for TLF at 1-year (6.7% vs 6.5% PE+ respectively, in the intent-to-treat population; P[noninferiority]=0.0005) and at 2-years TLF was 9.4% vs. 8.5%, respectively. Other event rates including death, MI and revascularization were low and not significantly different between groups. No additional ST events were observed with SYNERGY beyond day 6 (1 probable ST) through 2 years (2-year ST rate PE+ 0.8% vs SYNERGY 0.4%, *P*=0.3).

Conclusions: Over 2 years, SYNERGY provides comparable efficacy to PE+ with a lower relative rate of ST. Longer term follow up will provide insight into the presence and magnitude of clinical outcome differences between stent types. EVOLVE II 3-year clinical results will be presented.