The Svelte (New Providence, NJ) drug-eluting stent (DES) combines sirolimus with a novel, amino acid-based (PEA) bioabsorbable drug carrier. The stent is mounted on an Integrated Delivery System (IDS) consisting of a low compliant balloon with balloon control bands (BCBs) enveloping the balloon edges and affixed to a 0.014” wire, providing a very low profile, highly flexible drug-eluting coronary stent system specifically designed for direct stenting. The DIRECT I First-In-Man study (Webster, Ormiston et al., n=30) reported 0% clinically-driven MACE at 12-months with 2.7% stent volume obstruction (via IVUS) and 98% strut coverage (via OCT) observed at 6-months. All imaging was reviewed and adjudicated by independent core lab and DSMB.

Methods: The DIRECT II study is a prospective, randomized, active-control, multi-center, non-inferiority study comparing the safety and efficacy of the Svelte drug-eluting coronary stent IDS to the Medtronic Vascular (Santa Rosa, CA) Resolute Integrity(TM) DES. Preliminary results from the DIRECT-II Study: a prospective, randomized, active-control, multi-center, non-inferiority study with angiographic follow-up scheduled at 6-months to assess the primary endpoints of TVF and LL. Patients with symptomatic ischemic heart disease due to de novo stenotic lesions in arteries with RVD 2.5mm – 3.5mm and lesion length < 22mm were included. Stent evaluation post-procedure and at 6-month follow-up in 540 patients was also performed at sites with OCT capability. Additional clinical follow-up will take place through 5-years for all patients. Enrolment began January 2013 and will complete August 2013.

Results: Procedural and 30-day data on all patients, along with OCT image analysis, will be presented. Comparative data for time and cost savings, including overall procedural time, adjunctive product use, contrast use and radiation exposure, will be reported. We tried angiographic follow-up every year of the patients SES implanted. Conclusion: It is not remarkable change (4-year: 2.30±0.70, 5-year:2.26±0.74, 6-year: 2.21±0.58), 7.4% of 3-year follow-up patients, 5.5% of 4-year follow-up patients and 7.5% of 5-year follow-up patients are ruled out by revascularization.

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