Multicentre evaluation of a novel 120µm novolimus-eluting, fully coronary BRS: first report of six-month clinical and imaging endpoints


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THEME: Coronary Interventions

TOPI(S): Stable CAD, Stents and scaffolds

AIMS

The DESolve Cx study is a prospective, multi-center evaluation of the safety and efficacy of the DESolve® Cx Novolimus-Eluting Bioresorbable Coronary Scaffold System (BCSS) using clinical endpoints and multiple imaging modalities.

METHODS AND RESULTS

The DESolve Cx BCSS is a novel, thin strut (120 µm) drug eluting bioresorbable vascular scaffold (BRS) that combines a poly-L-lactide-based (PLLA-based) scaffold coated with a biodegradable PLLA-based polymer and the drug Novolimus, a macrocyclic lactone mTOR inhibitor with potent anti-proliferative properties. The scaffold drug dose is 5 µg per mm of scaffold length, and is currently available diameters of 2.5, 3.0, and 3.5 mm and lengths of 18 and 28 mm. The DESolve Cx scaffold differentiates itself from other BRS with thin struts minimizing areas of flow disturbance, and a shorter bioresorption time (>85% reduction in molecular weight within 6 months, 70% mass loss within 1 year, and bioresorption within 2 years). DESolve Cx scaffold also offers high expansion capacity without strut fracture. More rapid scaffold degradation, as demonstrated in the DESolve Nx study, allows for the earliest reported vessel and lumen growth and therefore early vascular restoration - the promise of BRS technology. A total of 50 patients with single, de novo coronary artery lesions were enrolled in this prospective, multi-center, single-arm registry. Those patients receiving the study device are being analysed for multiple clinical endpoints including: Major Adverse Cardiac Events (MACE), a composite endpoint of cardiac death, target vessel MI, or clinically-indicated target lesion revascularization (CI-TLR); Device and Procedure Success; Clinically-indicated Target Lesion and Target Vessel Revascularization, (CI-TVR) and Stent Thrombosis assessed at 1, 6 and 12 months and annually to 3 years. Baseline subject characteristics included 68% male, 60.0 ± 10.3 years of age, 20% presented with diabetes mellitus, 26% were current smokers, 84% and 70% had hypercholesterolemia and hypertension respectively. All patients underwent angiographic IVUS and OCT assessment at 6 months. Clinical and multimodality imaging results at 6 months will be presented.

CONCLUSIONS

The 120 µm DESolve® Cx Novolimus-Eluting BCSS offers unique characteristics and has demonstrated safety and efficacy in this study through 6 months. A report of the clinical and multimodality imaging results will be presented.

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