SIX-MONTH INTRAVASCULAR ULTRASOUND ANALYSIS OF THE DESOLVE FIM TRIAL WITH A NOVEL PLLA-BASED FULLY BIODEGRADABLE DRUG-ELUTING SCAFFOLD

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Background: The DESolve Bioresorbable Coronary Scaffold is a novel drug-eluting device combining a PLLA-based scaffold coated with a biodegradable poly lactide-based polymer and the drug Myolimus. Myolimus, a macrocyclic lactone mTOR inhibitor, has demonstrated potent anti-proliferative properties in two First-in-Man (FIM) trials using Elixir's metallic coronary stents. The drug dose is 3 mcg per mm of scaffold length. We aimed to present the IVUS results of the first-in-man evaluation of this novel scaffold.

Methods: The DESolve FIM trial enrolled 15 patients, treated with a single 3.0x14 mm DESolve at 3 European centers. IVUS was performed at the end of the procedure and repeated at six-month invasive follow-up. Complete and adequate IVUS images at baseline and follow-up were obtained for 11 cases. Serial changes in vessel volume, scaffold area and the degree of NIH formation were assessed. All analyses were performed by an independent core laboratory.

Results: For the first time with a biodegradable scaffold an increase in the device area was observed from baseline to 6 months by IVUS (from 5.35 ± 0.78 mm² to 5.61 ± 0.81 mm²). Additionally, there was no significant change in vessel volume (from 148.0 ± 37.0 mm³ to 150.03 ± 35.38 mm³) or area, demonstrating the absence of constrictive or expansive remodelling. There was very low neointimal volume (5.6 ± 2.8 mm³) and % scaffold obstruction (7.18 ± 3.37%), and no cases of incomplete strut apposition.

Conclusions: The DESolve scaffold demonstrated a unique property of expansion and no chronic recoil from baseline to follow-up. Results at 6 months showed effective neointimal suppression and no late strut malapposition thus suggesting a very efficacious and novel bioresorbable scaffold.