

## TCT@ACC-i2: Invasive and Interventional Cardiology

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

Moderated Poster Contributions

Poster Sessions, Expo North

Saturday, March 09, 2013, 10:00 a.m.-10:45 a.m.

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Session Title: Coronary Stents

Abstract Category: 47. TCT@ACC-i2: Coronary Intervention, Devices

Presentation Number: 2101M-224

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**Background:** The DESolve Bioresorbable Coronary Scaffold is a novel drug-eluting device combining a PLLA-based scaffold coated with a bioresorbable polylactide-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  $5.35 \pm 0.78 \text{ mm}^2$  to  $5.61 \pm 0.81 \text{ mm}^2$ ). Additionally, there was no significant change in vessel volume (from  $148.0 \pm 37.0 \text{ mm}^3$  to  $150.03 \pm 35.38 \text{ mm}^3$ ) or area, demonstrating the absence of constrictive or expansive remodelling. There was very low neointimal volume ( $5.6 \pm 2.8 \text{ mm}^3$ ) and % scaffold obstruction ( $7.18 \pm 3.37\%$ ). 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.