DEСolve NX Trial Clinical and Imaging Results

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On behalf of the DEСolve Nx Trial Investigators
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DE Solve Nx Clinical Trial Design

Primary Endpoint: 6-month in-scaffold late lumen loss
Secondary Endpoints:
- Clinical: Major Adverse Cardiac Events (cardiac death, target vessel MI, and clinically indicated TLR), Scaffold thrombosis
- QCA: In-segment late lumen loss, binary restenosis, and percent diameter stenosis
- IVUS: In-scaffold percent volume obstruction, malapposition
- OCT: In-scaffold percent obstruction, strut coverage
- MSCT: Percent diameter stenosis, lumen area

Single de novo Coronary Artery Lesion
Reference vessel diameter: 2.75-3.0mm
Lesion length: <12mm, DAPT 12 months
3.0, 3.25, 3.5mm diameters; 14 and 18mm lengths

13 International Sites
Europe, New Zealand and Brazil
126 patients

Clinical MACE
30d 6mo 1yr 1.5yr 2yr 3yr 4yr 5yr

Angiographic IVUS, OCT, MSCT (subset)

* Single Centre Subset
### Study Population
- **N = 126; NL = 126**
- **6 m Follow Up**
  - N = 120 (97.6%)
  - N_QCA = 113 (92%)*
  - 3 patients did not receive a study scaffold
  - 1 Death
  - 2 No contact**
  - 7 No follow up QCA
- **6m Imaging Subset Follow Up**
  - N_IVUS = 40 (87.0%)
  - N_OCT = 38 (83.0%)
  - IVUS: 40/46 with paired analysis
  - OCT: 38/46 patients with paired analysis
- **12 m Follow Up**
  - N = 119 (100%)
  - 1 Death
  - 2 Withdrew
- **24 m Follow Up**
  - N = 116 (100%)
  - 3 Deaths (1 cardiac; 2 non-cardiac)

### Patient Characteristics
- **N = 126**
- **Age, years (mean±SD)**: 62.0 ± 9.8
- **Male**: 68.3%
- **Diabetes mellitus**: 21.4%
- **Hypercholesterolemia**: 70.6%
- **Hypertension**: 70.6%
- **Previous MI**: 44.4%
- **Previous PCI**: 35.7%
- **Unstable Angina**: 12.7%

### Lesion Characteristics
- **N_L = 126**
- **Lesion Length, mm**: 11.2 ± 3.8
- **AHA/ACC Lesion class B2 / C**: 34.0%
- **Moderate / Heavy Calcification**: 18.3%
# QCA Results

<table>
<thead>
<tr>
<th>In-Scaffold Analysis</th>
<th>Baseline $N_L = 126$</th>
<th>Post procedure $N_L = 122^*$</th>
<th>6 months $N_L = 113$</th>
</tr>
</thead>
<tbody>
<tr>
<td>RVD (mm)</td>
<td>$3.00 \pm 0.29$</td>
<td>$3.05 \pm 0.25$</td>
<td>$2.96 \pm 0.28$</td>
</tr>
<tr>
<td>MLD (mm)</td>
<td>$0.91 \pm 0.38$</td>
<td>$2.64 \pm 0.28$</td>
<td>$2.44 \pm 0.43$</td>
</tr>
<tr>
<td>Acute gain (mm)</td>
<td></td>
<td>$1.72 \pm 0.43$</td>
<td></td>
</tr>
<tr>
<td>Acute Recoil (%)</td>
<td></td>
<td>6.4%</td>
<td></td>
</tr>
<tr>
<td>LLL at 6-months (mm)</td>
<td></td>
<td></td>
<td>$0.20 \pm 0.32$</td>
</tr>
<tr>
<td>Median Late Loss (mm)</td>
<td></td>
<td></td>
<td>$0.11 (0.03, 0.19)$</td>
</tr>
<tr>
<td>Diameter Stenosis (%)</td>
<td>$69.6 \pm 12.1$</td>
<td>$13.2 \pm 7.5$</td>
<td>$17.78 \pm 13.23$</td>
</tr>
<tr>
<td>In-Segment Binary Restenosis** n (%)</td>
<td></td>
<td></td>
<td>4 (3.5%)</td>
</tr>
</tbody>
</table>

Values are mean ± SD; % (n), or Median (interquartile range 25%, 75%).
MLD – Minimum luminal diameter; LLL – late lumen loss.
*Modified Intent to Treat = those patients in which a scaffold was implanted in target lesion
**In-Segment: In-scaffold ± 5mm proximal and distal to scaffold; 3 cases of geographic miss
Binary Restenosis Cases

Geographic miss distal

In-scaffold restenosis

Geographic miss proximal
Side Branch Analysis

<table>
<thead>
<tr>
<th>Side Branch Analysis</th>
<th>N = 71</th>
</tr>
</thead>
<tbody>
<tr>
<td>%DS at baseline</td>
<td></td>
</tr>
<tr>
<td>&lt; 50%</td>
<td>64</td>
</tr>
<tr>
<td>≥ 50%</td>
<td>7</td>
</tr>
<tr>
<td>Pre-TIMI 3 flow</td>
<td>68</td>
</tr>
<tr>
<td>SB wire</td>
<td>0</td>
</tr>
<tr>
<td>SB PTCA</td>
<td>0</td>
</tr>
<tr>
<td>% DS at postprocedure</td>
<td></td>
</tr>
<tr>
<td>&lt; 50%</td>
<td>39</td>
</tr>
<tr>
<td>≥ 50%</td>
<td>32</td>
</tr>
<tr>
<td>Post-TIMI flow 0 / 1 / 2 / 3</td>
<td>2 / 1 / 14 / 54</td>
</tr>
<tr>
<td>SB occlusion (TIMI 0 or 1)</td>
<td>3</td>
</tr>
</tbody>
</table>

DS = diameter stenosis; PTCA = percutaneous transluminal coronary angioplasty; SB = side branch; TIMI = Thrombolysis In Myocardial Infarction
Side Branch Analysis

- 71 SBs >1.0 mm were analyzed in 123 coronary segments treated by 126 scaffolds

- The majority of SBs (68/71 - 96%) had pre-procedure TIMI 3 flow

- During the procedure, neither guide wire protection nor intervention was performed in any SB

- At post-procedure, SB TIMI flow 0 or 1 was detected in only 3 cases, representing 4% SB occlusion rate

- Importantly, there were no adverse clinical events during hospitalization associated with SB occlusion
Serial IVUS Results
Scaffold and Lumen Area

$N_L = 40$

Post Procedure

<table>
<thead>
<tr>
<th>% volume obstruction</th>
<th>--</th>
<th>5.05 ± 4.20</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISA (n)</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>ISA Volume (mm³)*</td>
<td>0.70 ± 0.17</td>
<td>0.10</td>
</tr>
</tbody>
</table>

No Late Acquired ISA – No aneurysm formation

$N_L = $ Number of lesions.
Mean volume for patients with incomplete scaffold apposition (ISA),
One patient with persistent ISA
Serial OCT Results

Cross Sectional and Strut Level Analysis

In Scaffold Cross Sectional Analysis
(NL = 38)

Post procedure
6 m

In-scaffold Strut Level Analysis

<table>
<thead>
<tr>
<th>Frequency of covered Struts/patient (%)</th>
<th>Baseline</th>
<th>6 m</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>--</td>
<td>98.78 ± 1.69</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mean NIH thickness (mm)</th>
<th>Baseline</th>
<th>6 m</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>--</td>
<td>0.10 ± 0.03</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ISA (n)</th>
<th>Baseline</th>
<th>6 m</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>15</td>
<td>5</td>
</tr>
</tbody>
</table>

No late acquired ISA

NS: Number of Struts NL: Number of Lesions
Serial OCT Results

NIH Thickness and Distribution

Mean NIH Thickness: 100.53 ± 30.58 μm
Serial OCT Results

Strut Coverage into Perspective

Frequency of Uncovered Struts per Patient

- DESolve 6M
- ABSORB 6M
- Cypher non-OLP (ODESSA) 6M
- CoCr-EES (EVEREST) 6M
- Pt-Cr-EES (EVEREST) 6M
- Taxus non-OLP (ODESSA) 6M
- Taxus (OCTDESII) 6M
- Taxus (OCTAXUS) 6M
- Endeavor non-OLP 6M
- BMS non-OLP 6M

Values in the diagram:
- DESolve 6M: 1.21%
- ABSORB 6M: 3.23%
- Cypher non-OLP (ODESSA) 6M: 8.85%
- CoCr-EES (EVEREST) 6M: 5.88%
- Pt-Cr-EES (EVEREST) 6M: 8.46%
- Taxus non-OLP (ODESSA) 6M: 2.71%
- Taxus (OCTDESII) 6M: 5.30%
- Taxus (OCTAXUS) 6M: 2.91%
- Endeavor non-OLP 6M: 0.02%
- BMS non-OLP 6M: 0.56%
12-month MSCT Results

<table>
<thead>
<tr>
<th>In-scaffold Analysis</th>
<th>12-month Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reference Diameter (mm)</strong></td>
<td>2.9 ± 0.5</td>
</tr>
<tr>
<td><strong>Minimal Lumen Diameter (mm)</strong></td>
<td>2.3 ± 0.5</td>
</tr>
<tr>
<td><strong>Mean Diameter Stenosis (%)</strong></td>
<td>21.8 ± 12.3</td>
</tr>
<tr>
<td><strong>Mean Lumen area (mm(^2))</strong></td>
<td>5.5 ± 2.2</td>
</tr>
<tr>
<td><strong>Minimum Lumen area (mm(^2))</strong></td>
<td>4.8 ± 2.6</td>
</tr>
<tr>
<td><strong>Reference area (mm(^2))</strong></td>
<td>7.3 ± 2.6</td>
</tr>
<tr>
<td><strong>Mean area stenosis (%)</strong></td>
<td>33.2 ± 17.8</td>
</tr>
</tbody>
</table>

*MLD and % DS maintained between 6 and 12 months*
# Imaging Modalities Comparisons

## In-scaffold Analysis

<table>
<thead>
<tr>
<th>In-scaffold Analysis</th>
<th>12-month Follow-up N = 41</th>
<th>6-month QCA</th>
<th>6-month IVUS</th>
<th>6-month OCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Reference Diameter (mm)</td>
<td>2.9 ± 0.5</td>
<td>3.0 ± 0.3</td>
<td>3.7 ± 0.8</td>
<td>n/a</td>
</tr>
<tr>
<td>Mean Lumen Diameter (mm)</td>
<td>2.5 ± 0.5</td>
<td>2.9 ± 0.3</td>
<td>2.8 ± 0.3</td>
<td>2.7 ± 0.3</td>
</tr>
<tr>
<td>Mean Lumen area (mm²)</td>
<td>5.5 ± 2.2</td>
<td>n/a</td>
<td>6.4 ± 1.2</td>
<td>5.8 ± 1.2</td>
</tr>
<tr>
<td>Minimum Lumen area (mm²)</td>
<td>4.8 ± 2.6</td>
<td>n/a</td>
<td>4.7 ± 1.1</td>
<td>4.8 ± 1.0</td>
</tr>
<tr>
<td>Minimum Lumen Diameter (mm)</td>
<td>2.3 ± 0.5</td>
<td>2.5 ± 0.4</td>
<td>2.1 ± 0.3</td>
<td>2.4 ± 0.2</td>
</tr>
<tr>
<td>Mean area stenosis (%)</td>
<td>33.2 ± 17.8</td>
<td>n/a</td>
<td>26.1 ± 8.8</td>
<td>27.9 ± 10.7</td>
</tr>
</tbody>
</table>

Minimum lumen area and minimum lumen diameter maintained between 6 and 12 months
DESolve NX Clinical Trial Update

Study Population
N = 126; NL = 126

6 m Follow Up
N = 120 (97.6%)
N_{QCA} = 113 (92%)*

3 patients did not receive a study scaffold
1 Death
2 No contact**
7 No follow up QCA

6m Imaging Subset Follow Up
N_{IVUS} = 40 (87.0%)
N_{OCT} = 38 (83.0 %)

IVUS: 40/46 with paired analysis
OCT: 38/46 patients with paired analysis

12 m Follow Up
N = 119 (100%)

1 Death
2 Withdrew

24 m Follow Up
N = 116 (100%)

3 Deaths
(1 cardiac; 2 non-cardiac)

* Patients who received a study scaffold;
** Patients returned for 12 month visit; ^MITT analysis
Mean LL at 6 mos: 0.25
Mean LL at 18 mos: 0.32
Mean change between 6 and 18 mos: 0.07

Median LL at 6 mos: 0.13
Median LL at 18 mos: 0.24
Median Change between 6 and 18 mos: 0.04

* Paired analyses
## 6 to 24-month Clinical Outcomes

<table>
<thead>
<tr>
<th>Hierarchical Events</th>
<th>6M (N=122)*</th>
<th>12M (N=122)*</th>
<th>24M (N=122)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Major Adverse Cardiac Events</strong></td>
<td>3.3%</td>
<td>5.7%</td>
<td>7.4%</td>
</tr>
<tr>
<td>Cardiac Death**</td>
<td>1 (0.8%)</td>
<td>2 (1.6%)</td>
<td>3 (2.5%)</td>
</tr>
<tr>
<td>Target vessel MI***</td>
<td>1 (0.8%)</td>
<td>1 (0.8%)</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>Q-wave MI</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Non-Q-wave MI</td>
<td>1 (0.8%)</td>
<td>1 (0.8%)</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>Clinically Indicated-TLR PCI</td>
<td>2 (1.6%)</td>
<td>4 (3.3%)</td>
<td>5 (4.1 %)</td>
</tr>
<tr>
<td>Definite Stent Thrombosis†</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
</tbody>
</table>

*Modified Intent to Treat = those patients in which a scaffold was implanted in target lesion

**One death with probable ST based on ARC, scaffold undersized as assessed by IVUS; one death with suspected pulmonary embolus with right heart failure, non-scaffold related; one death due to non-target vessel occlusion and PCI, non-scaffold related

***MI during follow up attributed to multi modality imaging procedure + ARC-defined
DE Solve Bioresorbable Scaffold

Conclusions

The DE Solve Nx pivotal trial was successful in demonstrating safety and efficacy of the DE Solve Scaffold

- **Efficacy:**
  - Low 6-month late lumen loss by QCA at 0.21 ± 0.32 mm
  - Low 6-month IVUS % Volume obstruction at 5%
  - Low 6-month NIH thickness 0.10 mm by OCT
  - Sustained neointimal suppression through 18 months

- **Safety:**
  - Low 24-month MACE rate at 7.4%
  - No late acquired ISA by IVUS / OCT at 6 months
  - High percentage of strut coverage (98.8%) by OCT at 6 months
  - Side branch occlusion was rate was low and not associated with adverse clinical events

Clinical results mirror preclinical finding of vascular restoration within 6 months as evidenced by lumen growth