Early safety and feasibility of the DurAVR™
first-in-class biomimetic transcatheter aortic valve

Susheel K. Kodali, MD
Columbia University Irving Medical Center, New York, New York, USA
I have the following potential conflicts of interest to report:

- Consultant: Anteris Technologies, TRiCares, TriFlo Cardiovascular, xDot Medical, Micro Interventional Devices, Supira Medical, Adona Medical, Tioga Cardiovascular, HVR Cardio Helix Valve Repair, Moray Medical

- Scientific Advisory Board Member: Dura Biotech, Thubrikar Aortic Valve Inc, Philips, Medtronic, Boston Scientific, Abbott Laboratories

- Institutional Research Funding recipient: Edwards Lifesciences, Medtronic, Abbott Vascular, Boston Scientific, JenaValve Technology
DurAVR™: A First-in-class Biomimetic Transcatheter Aortic Valve

**DurAVR™ THV System**

- Native-like shaped valve
- Balloon-expandable large cells
- ADAPT® Anti-Calcification Tissue Engineering Process
- Commissure alignment
- Single-piece leaflet design
- PVL skirt

**Biomimetic valve**

**ComASUR™ TF Delivery System**
**DurAVR™ FIH Study Design**

**Design**
Prospective, non-randomised, single-arm, single-centre

**Purpose**
Evaluate the safety and feasibility of the DurAVR™ THV System (Anteris Technologies, USA)

**Population**
20 subjects with severe symptomatic AS

**Follow-up**
Clinical, echo, MDCT, and cardiac MRI performed. Follow-up to 1 year.
### Baseline and Procedural Characteristics

#### Baseline characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n = 20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>74.25 ± 5.72</td>
</tr>
<tr>
<td>Gender (female)</td>
<td>16 (80)</td>
</tr>
<tr>
<td>STS Prom (%)</td>
<td>2.25 ± 0.90</td>
</tr>
<tr>
<td>Area-derived annulus diameter (mm)</td>
<td>22.73 ± 1.25</td>
</tr>
<tr>
<td><strong>NYHA class</strong></td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>16 (80)</td>
</tr>
<tr>
<td>III</td>
<td>4 (20)</td>
</tr>
<tr>
<td><strong>Risk factors</strong></td>
<td></td>
</tr>
<tr>
<td>CAD</td>
<td>15 (75)</td>
</tr>
<tr>
<td>Conduction disturbances</td>
<td>11 (55)</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>5 (25)</td>
</tr>
<tr>
<td>Past MI</td>
<td>4 (20)</td>
</tr>
<tr>
<td>Obesity</td>
<td>4 (20)</td>
</tr>
<tr>
<td>Diabetes type II</td>
<td>4 (20)</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>11 (55)</td>
</tr>
<tr>
<td>Permanent pacemaker</td>
<td>1 (5)</td>
</tr>
</tbody>
</table>

#### Procedural characteristics

<table>
<thead>
<tr>
<th>Approach</th>
<th>n = 20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfemoral (TF)</td>
<td>14 (70)</td>
</tr>
<tr>
<td>Transaortic (T Ao)*</td>
<td>5 (25)</td>
</tr>
<tr>
<td>Transcarotid (TC)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>General anesthesia</td>
<td>20 (100)</td>
</tr>
<tr>
<td>Pre-BAV</td>
<td>20 (100)</td>
</tr>
<tr>
<td>Post-BAV</td>
<td>16 (80)</td>
</tr>
</tbody>
</table>

* Performed prior to development of the ComASUR TF Delivery System

#### Challenging anatomies treated (Baseline MDCT)

- Severe annular calcium
- Extreme leaflet calcium
- Type 1 bicuspid
- Extreme LVOT calcium

Data presented as mean ± SD or n(%)
Procedural Outcomes

100% Implant Success

- No device-related complications
- No moderate or severe paravalvular leak (PVL)
- One mild-moderate central AR (early case before valve sizing optimization)
- No significant PVL and no central AR post-optimization

Balloon-expandable delivery (easy to implant)
Large open-cell geometry (easy to access coronaries)
Mean coaptation length 8.3 mm

AR = Aortic Regurgitation
Excellent Post-Procedure Haemodynamics (48h TTE)

**EOA (cm²)**

- Baseline: 0.69
- Post-procedure: 2.12

**EOAi (cm²/m²)**

- Baseline: 0.39
- Post-procedure: 1.18

**DVI**

- Baseline: 0.20
- Post-procedure: 0.61

**MPG (mmHg)**

- Baseline: 53.34
- Post-procedure: 8.66

Mean annulus: 22.73 mm (n=20)
Consistent Excellent Haemodynamic Results up to 1 Year Follow-up

Mean annulus: 22.95 mm
(n=13)

Baseline (n=13)
30 Days (n=13)
6 Months (n=13)
1 Year (n=5)

EOA (cm²)

MPG (mmHg)

EOA = Effective Orifice Area
MPG = Mean Pressure Gradient
Favourable Safety Profile in All Patients at Latest Follow-up

✓ No deaths
✓ No stroke
✓ No minor or major bleeding
✓ No reoperation or reintervention
✓ No moderate or severe prosthesis-patient mismatch
✓ One access site complication (resolved on POD 1)
✓ One new pacemaker in a patient with baseline RBBB and LAFB (POD 6)

AR = Aortic Regurgitation, LAFB = Left Anterior Fascicular Block, POD = Post Operative Day, RBBB = Right Bundle Branch Block
DurAVR™: the First-In-Class Biomimetic THV To Restore Normal Aortic Flow

**Healthy Aortic Valve**

- FD = 10cm  
  - FRR = 1%  
  - (n=5)

**Post DurAVR™ THV**

- FD = 14cm  
  - FRR = 4%  
  - (n=5)

**Impaired Aortic Flow**

- **Severe AS**
  - FD = 46cm  
  - FRR = 23%

- **Edwards Sapien 3**
  - FD = 48cm  
  - FRR = 35%

- **Medtronic Evolut R**
  - FD = 25cm  
  - FRR = 4%

- **CEP Magna Ease**
  - FD = 27cm  
  - FRR = 30%

**Normal Valves**

- (n=5) vs **TAVI** (n=4): **p < 0.05**

- (n=5) vs **SAVR** (n=8): **p < 0.01**

Normal Valve vs DurAVR™: **No significant difference** in flow (p > 0.05)

*Courtesy of Dr. Pankaj Garg*
Early safety and feasibility of a first-in-class biomimetic transcatheter aortic valve (DurAVR)

Susheel K. Kodali¹, MD; Paul Sorajja², MD; Christopher U. Meduri³, MD; Kari Feldt⁴, MD; João L. Cavalcante⁵, MD; Pankaj Garg⁶, PhD; Nadira Hamid⁷, MD; Karl K. Poon⁸, MD; Magnus R.M. Settergren⁹, MD, PhD; Marcus R. Burns⁴, DNP; Andreas Rück³, MD; Janarthanan Sathanathan⁸, MD; Alan Zajarias⁹, MD; Tamaz Shaburishvili¹⁰, MD; Teona Zirakashvili¹⁰, MD; Maia Zhividze¹⁰, MD; George Katchakhidze¹¹, MD; Vinayak Bapat¹², MBBS, MS, MCh, FRCS (Ed), FCRS (CTh)

1. Columbia University Irving Medical Center, New York, NY, USA; 2. Minneapolis Heart Institute, Abbott Northwestern Hospital, Minneapolis, MN, USA; 3. Department of Cardiology, Karolinska University Hospital, Stockholm, Sweden; 4. Department of Medicine, Solna, Karolinska Institutet, Stockholm, Sweden; 5. Norwich Medical School, University of East Anglia, Norwich, UK; 6. Norfolk and Norwich University Hospitals NHS Foundation Trust, Norwich, UK; 7. St. Andrew’s War Memorial Hospital, Brisbane, QLD, Australia; 8. St. Paul’s Hospital, Vancouver, BC, Canada; 9. Washington University School of Medicine, St. Louis, MO, USA; 10. Cardiovascular Clinic, Tbilisi Heart and Vascular Clinic, Tbilisi, Georgia; 11. Aversi Clinic, Tbilisi, Georgia

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