DurAVR™ Transcatheter Aortic Valve First-in-Human Study: Impact of Novel Leaflet Design

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I have the following potential conflicts of interest to report:

CMO: Anteris Technologies

Receipt of grants / research support: Boston Scientific

Receipt of honoraria or consultation fees: Abbott, Alleviant, Boston Scientific, Cardiovalve, VDyne, XDot
TAVI Consists of Compromises
Current TAVR platforms impair optimal lifetime management strategies

Balloon Expandable Advantages

- ✓ Short frame height
- ✓ Ease of use

Self Expandable Advantages

- ✓ Optimal Haemodynamics*
- ✓ Commissure alignment

DurAVR™ THV

- ✓ Native Leaflet Design
- ✓ Advanced Acellular Tissue

Potential Future

- ❑ Native-like flow dynamics
- ❑ Lower immunogenicity

* Schmidt S., Clin Res Cardiol 2022, doi: 10.1007/s00392-022-02046-7
A valve designed to 

**Restore** near-normal hemodynamic function

For **Better** coaptation and less leaflet stress

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**NEAR-NORMAL HEMODYNAMICS**

Unique single-piece valve design for larger EOA and lower gradients

**PROVEN TISSUE DURABILITY**

Superior anti-calcification tissue process (ADAPT®)*

- DNA and glutaraldehyde free
- 10 years in clinical use

**IMPROVED CORONARY ACCESS**

Large, open cell geometry

**ComASUR™ TF DELIVERY SYSTEM**

Balloon Expandable system with ability to uniquely rotate valve for predictable commissural alignment

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Graphical representation of the single-piece geometry of DurAVR™ THV (left), and standard balloon-expandable TAVI devices (right).

* Neethling, JHVD 2008; JHVD 2010; ICVTS 2018.
  Briand, JTCVS 2014; doi:10.1016/j.jtcvs.2014.08.002.
  Neethling, Front Ped. 2020; doi.org/10.3389/fped.2020.00198

PCRLondonValves.com
**DurAVR™ FIH Study Design & Baseline Characteristics**

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

### Purpose
- Evaluate the safety and feasibility of the DurAVR™ THV System

### Population
- 13 subjects with severe symptomatic AS

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

### Baseline characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>73.92 ± 6.4</td>
</tr>
<tr>
<td>Gender (female)</td>
<td>77%</td>
</tr>
<tr>
<td>STS Prom (%)</td>
<td>2.34 ± 1.07</td>
</tr>
<tr>
<td>Area-derived annulus diameter (mm)</td>
<td>22.95 ± 1.09</td>
</tr>
<tr>
<td>NYHA class</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>85%</td>
</tr>
<tr>
<td>III</td>
<td>15%</td>
</tr>
</tbody>
</table>

### Challenging anatomies treated (Baseline MDCT)

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

MDCT = Multidetector Computed Tomography
MRI = Magnetic Resonance Imaging
Procedural Results

100% Procedural Success

- Rotation for Alignment
- Deployment

- Mean coaptation length 8.3 mm

- No moderate or severe paravalvular leak
- One mild/moderate central AR (early case before valve sizing optimization)
Clinical Outcomes

✓ No deaths
✓ No stroke
✓ No minor or major bleeding
✓ No reoperation or reintervention
✓ No myocardial infarction
✓ No device-related complications
✓ 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
Unique Native Like Leaflets Result in Native Like Function

Restores Normal Aortic Flow Dynamics

Consistent laminar flow throughout valve

Native valve-like leaflet function

30 Days Echo

30 Days MDCT
Exceptional Hemodynamic Results at 30 Days in BE Platform

**Mean annulus size: 22.95 mm**

<table>
<thead>
<tr>
<th></th>
<th>EOA (cm²)</th>
<th>EOAi (cm²/m²)</th>
<th>MPG (mmHg)</th>
<th>DVI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline</strong></td>
<td>0.50</td>
<td>0.27</td>
<td>49.25</td>
<td>0.20</td>
</tr>
<tr>
<td><strong>30 Days</strong></td>
<td>2.00</td>
<td>1.15</td>
<td>9.02</td>
<td>0.53</td>
</tr>
</tbody>
</table>

**Mean annulus size: 22.95 mm**
DurAVR™: First AVR Shown to Restore Normal Aortic Flow

**Healthy Aortic Valve**

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

**Post DurAVR THV**

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

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

**Impaired Aortic Flow**

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

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

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

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

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

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

*Courtesy of Dr. Pankaj Garg*
DurAVR™: Challenging the AS Treatment Paradigm

- Provides the benefits of balloon expanding and self-expanding valve in one platform
- Restores normal function through unique single-piece native shaped valve
- FIH study shows remarkable safety and hemodynamic performance (EOA = 2.0 cm² with mean annulus of 22.95 mm and area = 411 mm²)
- The first AVR (TAVR or SAVR) to demonstrate restoration of normal flow dynamics
- Further studies needed to understand restoration of normal flow dynamics impact on: Durability, Myocardial recovery, Myocardial remodeling, Aortopathies, Thrombosis
Anteris DurAVR™ THV System

*Designed to Last Longer & Work Better*

For further information