# Anteris Technologies Global Corp.

December 2024

ANTERISTECH.COM

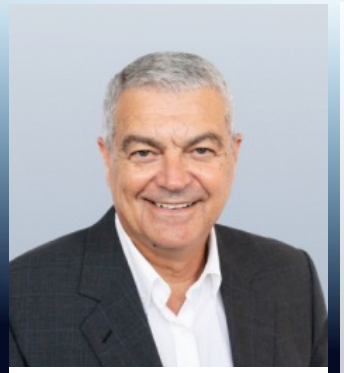
# BOARD OF DIRECTORS

**John Seaberg**
**Chairman**

- Anteris Chair since 2017 and director since October 2014
- Chair of Preceptis Medical Inc since 2016 and Phraxis Medical Inc since 2009
- Executive VP at Cedar Point Capital, a broker-dealer focused on healthcare investment from 2015 until Dec 2023
- Chair of Synovis Inc., from 2008-2012, a NASDAQ-listed manufacturer of medical device and bio scaffold tissue products (acquired by Baxter)
- Co-Founder, Chair and CEO of NeoChord Inc., from 2007 until 2014
- Various executive level positions, including Director of Marketing for Cardiac Rhythm Management, VP of Sales for Cardiac Surgery and VP of Sales for Cardiac Rhythm Management at Guidant Corp. (subsequently acquired by Boston Scientific) from 1996 to 2006
- Co-Founder, President and CEO of ACIST Medical, from 1991 to 1995
- Bachelor of Arts Speech Communications, University of Minnesota and MBA, Carlson School of Management, University of Minnesota

**Wayne Paterson**
**Managing Director & CEO**

- Joined Anteris in October 2014 as a Non-Executive Director, served as Chair from February 2016 to March 2017, Interim CEO from May 2016, and CEO and Managing Director since March 2017
- Chair of v2vmedtech, inc. from March 2023
- Non-Executive Director Cepheid Inc. (Molecular Diagnostics) (NASDAQ:CHPD) 2015 to 2016
- Senior positions at Merck KGaA (“Merck”) from 2005 to 2013, including President of Europe, Canada and Australia, President of Emerging Markets, President of Japan and President of Cardiovascular Medicine
- Senior positions at Roche Pharmaceuticals from 1999 to 2005, including Head of Pharmaceuticals in Roche’s South Korean operation and Head of Commercial Operations for Roche China
- MBA from the University of Southern Queensland and a degree in Business Studies from the Queensland University of Technology



**Stephen Denaro**
**Director**
**Company Secretary**

- Director since October 2018, Anteris Company Secretary since 2018
- Provision of company secretarial services to other ASX-listed companies since 1994, and director and sole shareholder of Trio Business Intermediaries Pty Ltd, a business consulting company, specialising in restructuring, corporate governance, directorship and company secretarial services
- Over 25 years of experience in M&A, business valuations, accountancy services, and income tax compliance gained from positions as Company Secretary and CFO of various public companies and major chartered accountancy firms in Australia and the United Kingdom
- Bachelor of Business in Accountancy, Graduate Diploma in Applied Corporate Governance and member of the Institute of Chartered Accountants in Australia & New Zealand, and the Australian Institute of Company Directors

**Dr. Wenyi Gu**
**Non-Executive Director**

- Director since October 2018
- Guest professor with several Chinese institutes and universities
- Research Fellow for the Australian Institute for Bioengineering and Nanotechnology at the University of Queensland since Jan 2017
- Chief Scientific Officer of Guangzhou Gillion Biotherapeutics Ltd, a biotechnology company from April 2021 to March 2023
- Master’s degree in veterinary science and PhD in biochemistry and molecular biology, Australian National University, later worked at John Curtin Medical School
- Held a Peter Doherty Fellowship (2006-2009) and was supported by the National Health and Medical Research Council to work at Harvard Medical School, Harvard University as a visiting fellow

# EXECUTIVE LEADERSHIP TEAM

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**David St. Denis**
**Chief Operating Officer**

- Chief Operating Officer since July 2017
- Chief Executive Officer of v2vmedtech, inc. since 2023
- Head of Commercial Operations for Europe and Canada at Merck from 2013 to 2017
- Head of Operations for Emerging Markets at Merck since 2008 to 2013
- Strategic consulting services from 2006 to 2008
- Multiple leadership roles at Millennium Pharmaceuticals, Inc, now Takeda Pharmaceutical Company, from 1996 to 2006
- Bachelor of Science, the University of Connecticut, a Master of Arts from Boston University and an MBA in Global Management and International Marketing from Babson College – Franklin W. Olin Graduate School of Business

**Matthew McDonnell**
**Chief Financial Officer**

- Chief Financial Officer since November 2018
- Chief Financial Officer of v2vmedtech, inc. from March 2023
- 30 years of experience in Finance
- Previous experience at KPMG across Australia and the US, covering the financial services, transport, industrial markets, health, childcare and energy industries
- Director of the State Library of Queensland where he was the Chair of the Audit and Risk Management Committee for 8 years
- Bachelor of Economics from Macquarie University, Associate of Chartered Accountants in Australia and New Zealand, a Fellow of the Financial Services Institute of Australasia and a Member of the Australian Institute of Company Directors

**Dr. Chris Meduri**
**Chief Medical Officer**

- Chief Medical Officer since 2021 after serving on the advisory board since 2016
- Practicing Interventional Cardiologist at Karolinska University Hospital, Stockholm, Sweden and recognized global leader in the field of valvular heart disease with over 3,500 career structural heart procedures and over 300 annually
- Served as global head of numerous TAVR, mitral and tricuspid trials. Has participated in 16 early feasibility studies and performed numerous first-in-human, first-in-US and first-in-Europe procedures
- Completed his general, interventional and structural heart disease training at Beth Israel Deaconess Medical Center, Harvard Medical School
- Masters in Public Health (MPH) with a focus on Clinical Effectiveness at the Harvard School of Public Health. He completed his internship and residency in Internal Medicine at Duke University

## MEDICAL ADVISORY BOARD

# Anteris is guided by a global team of well regarded cardiovascular Physician advisors

### North America

**Martin Leon, MD**
Columbia Medical Center Cardiovascular Research Foundation
New York, NY

**Michael Reardon, MD**
Houston Methodist
Houston, TX

**Samir Kapadia, MD**
Cleveland Clinic
Cleveland, OH

**Gorav Ailawadi, MD**
Univ of Virginia
Charlottesville, VA

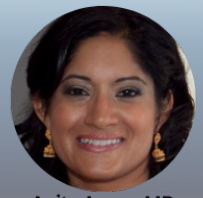
**Alan Zajarias, MD**
Washington Univ
St. Louis, MO

**Joao Cavalcante, MD**
Abbott Northwestern
Minneapolis, MN

**Susheel Kodali, MD**
Columbia Medical Center
New York, NY

**Vinayak Bapat, MD**
Abbott Northwestern
Minneapolis, MN

**Rebecca Hahn, MD**
Columbia Medical Center
New York, NY

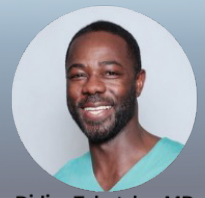


**Anita Asgar, MD**
Montreal Heart
Montreal, CA

### Europe

**Nicolas Van Mieghem MD**
Erasmus Univ Med Center
Rotterdam, NL

**Thomas Modine, MD**
CHU de Bordeaux
Bordeaux, FR



**Didier Tchetche, MD**
Clinique Pasteur
Toulouse, FR

**Magnus Settergren, MD**
Karolinska Uni Hospital
Stockholm, SE

### Australia

**Karl Poon, MBBS**
St Andrews War Memorial
The Prince Charles Hospital, Brisbane

**Jayme Bennetts, MBBS**
Flinders Medical Center, Adelaide

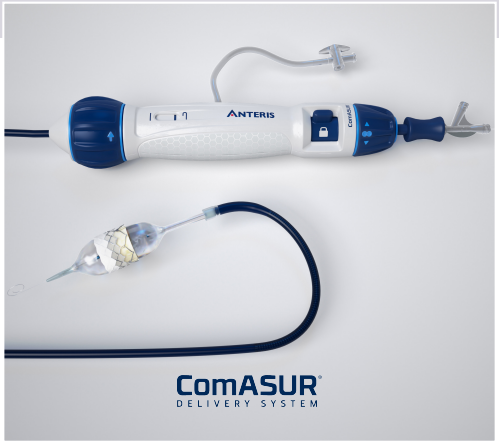
**Ajay Sinhal MBBS, MD**
Flinders Medical Centre, Adelaide

**Dion Stub MBBS, PhD**
The Alfred/ Cabrini Hospital, Melbourne

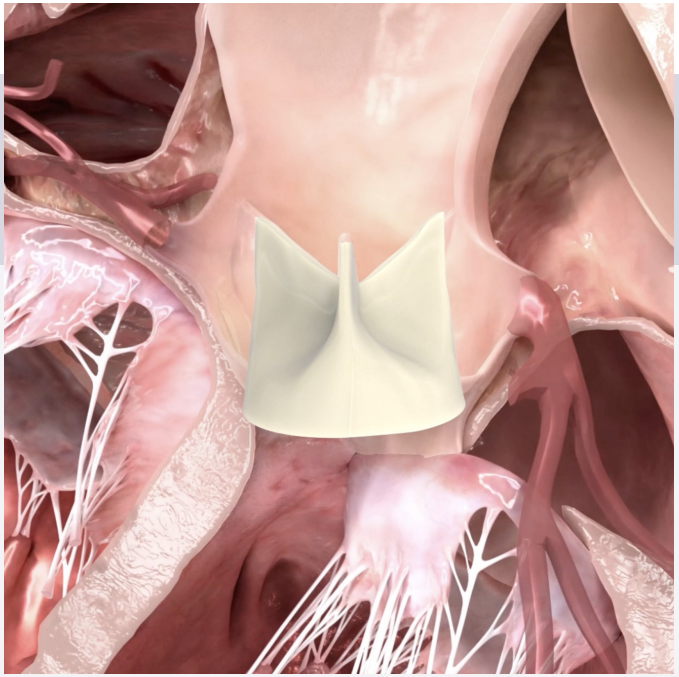
# DurAVR®
TRANSCATHETER HEART VALVE

## The first new class of TAVR in over a decade

### Balloon expandable delivery system




- Simple & precise deployment
- Commissure alignment



### The first in class biomimetic valve

Uniquely shaped to mimic the performance of a healthy aortic valve

### Promising hemodynamic performance[1]


- The only valve to restore flow dynamics
- Biomimetic design leads to restoration of laminar flow

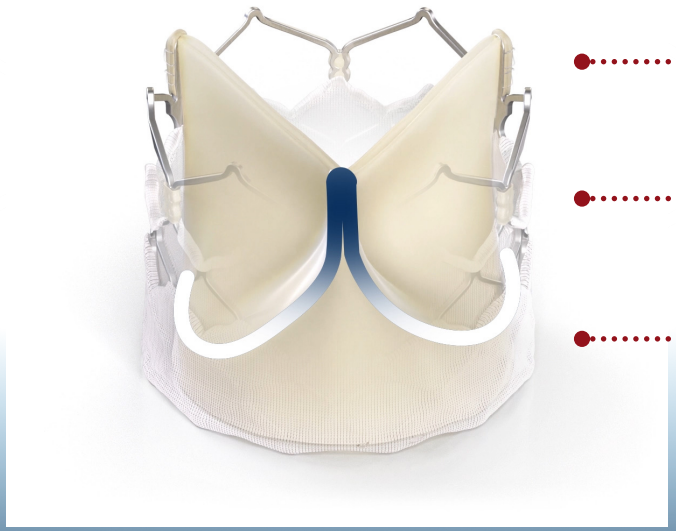
*1. Cavalcante J. Biomimetic Design Restores Flow and Hemodynamics and Leads to Significant LV Mass Regression: update from First-in-Human (FIH) Study with novel DurAVR® Transcatheter Heart Valve. Oral Presentation at: New York Valves; June 2024; New York, New York.*

DurAVR®
TRANSCATHETER HEART VALVE

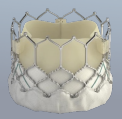
# Proprietary innovation that leads to a more human like valve

**"A balloon expandable valve with self-expanding hemodynamics is like the Holy Grail[1]."**

**Dr Michael Reardon,**
**Professor of Cardiothoracic Surgery**



- Large open cells in stent frame to improve coronary access
- Designed to be anatomically correct, intended to restore normal laminar flow[2]
- Single piece design intended to provide greater structural integrity and durability vs traditional three piece design



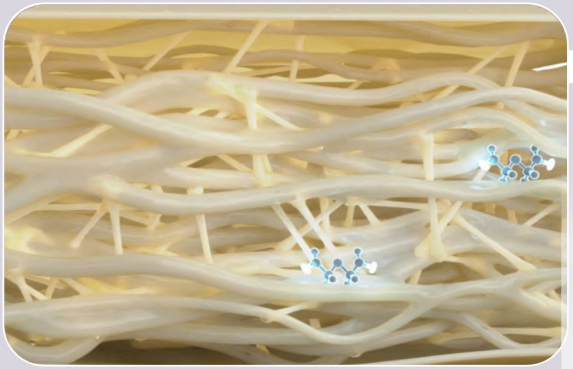
**Balloon Expandable Advantages**
- **Short frame height**
- **Ease of use**
- **Predictability**

**Self Expandable Advantages**
- **Optimal hemodynamics**
- **Commissure alignment**

1. PCR London Valves 2023
2. Garg P, Markl M, Sathananthan J, Sellers SL, Meduri C, Cavalcante J. Restoration of flow in the aorta: a novel therapeutic target in aortic valve intervention. Nat Rev Cardiol. 2024 Apr;21(4):264-273. doi: 10.1038/s41569-023-00943-6. Epub 2023 Oct 25. PMID: 37880496.

# Three Highly Innovative Technologies

Anteris aims to address unmet medical needs with a new class of products for the treatment of aortic stenosis.
This new class of biomimetic technology can be used for new patients and to replace existing valves in patients (valve-in-valve ("ViV")).




**ADAPT® for life**

- **FDA approved tissue since 2014**
- **Distributed for use in over 55,000 patients globally (as a cardiac and vascular patch)**
- **Clinically demonstrated to be calcium free for up to 10 years[1]**

**DurAVR®**
TRANSCATHETER HEART VALVE

- **Novel biomimetic valve**
  - **Shaped to perform like a native aortic valve**
- **Single piece of tissue**
- **Improved coronary access**
- **US patent protected design (11,648,107 and 11,622,853)**

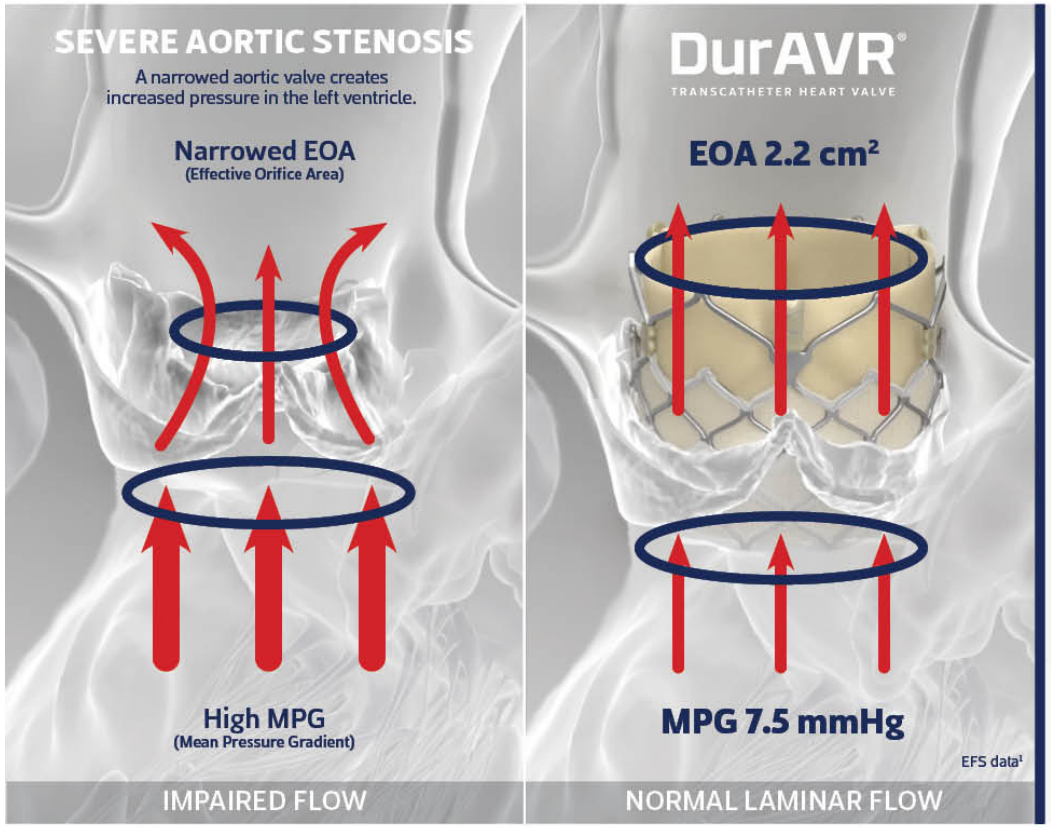
**ComASUR®**
TRANSFEMORAL DELIVERY SYSTEM

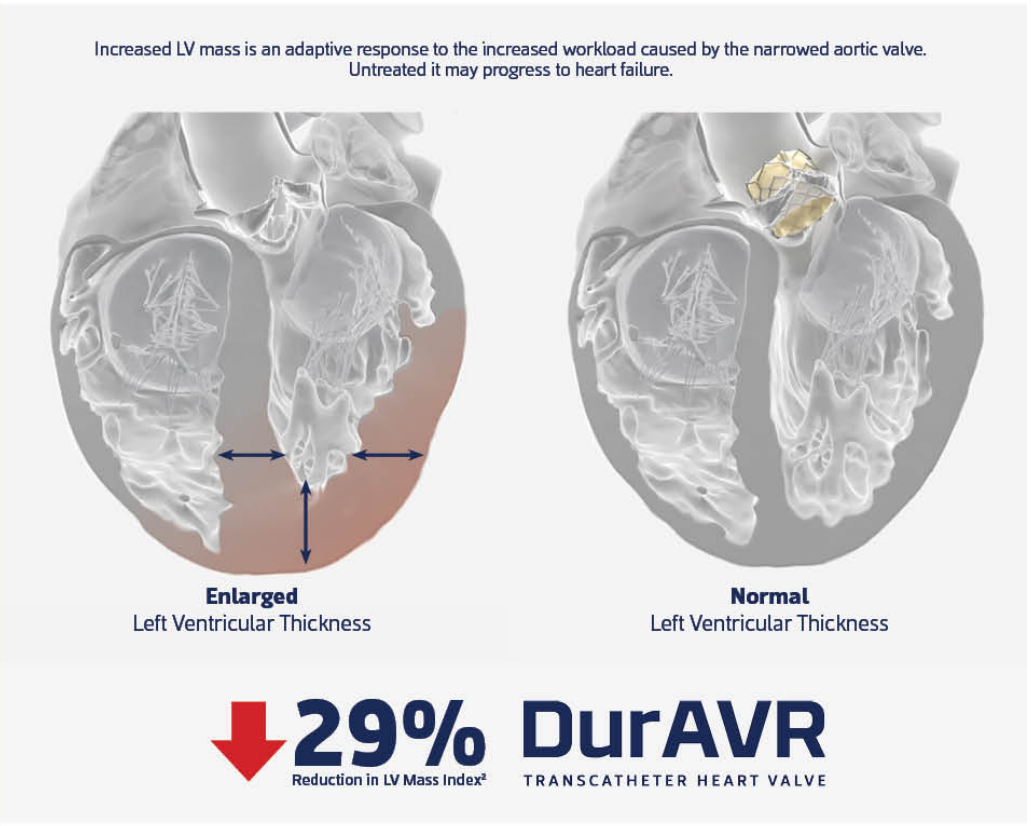
- **Balloon expandable platform**
- **Provides controlled deployment and accurate alignment of the DurAVR® THV valve with the position of the native aortic valve**
- **Patent for the sterilized packaging system**

1. Neethling W, Rea A, Forster G, Bhirangi K. Performance of the ADAPT-Treated CardioCel® Scaffold in Pediatric Patients With Congenital Cardiac Anomalies: Medium to Long-Term Outcomes. Front Pediatr. 2020 Apr 24;8:198. doi: 10.3389/fped.2020.00198. PMID: 32391296; PMCID: PMC7193326.

DurAVR®
TRANSCATHETER HEART VALVE

# Restores flow dynamics, significantly reducing left ventricular (LV) mass




1. Waggoner T. "DurAVR® Biomimetic Transcatheter Heart Valve: Early Feasibility Study (EFS) Update". Oral Presentation at: CRT Conference, March 2024; Washington, USA
2. Cavalcante J. Biomimetic Design Restores Flow and Hemodynamics and Leads to Significant LV Mass Regression: update from First-in-Human (FIH) Study with novel DurAVR® Transcatheter Heart Valve. Oral Presentation at: New York Valves; June 2024; New York, New York..

# DurAVR® US Early Feasibility Study

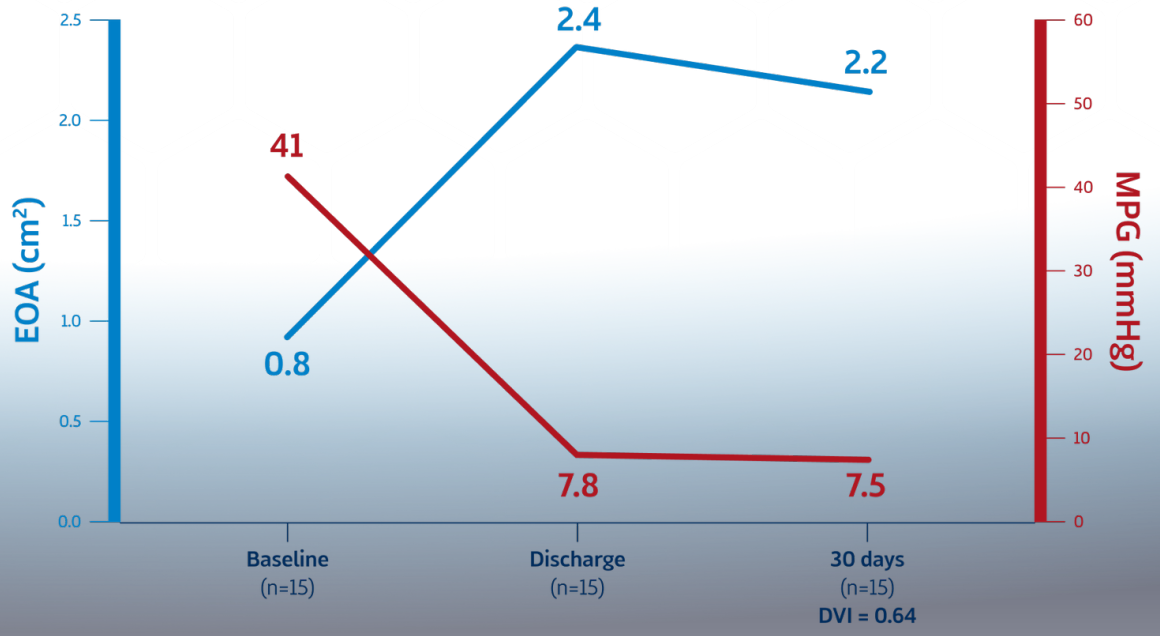
Promising 30-day hemodynamic (blood flow) results*
Favorable safety profile, no paravalvular leak at 30-day follow up

**Effective Orifice Area (EOA)**

- The cross–sectional area of the aortic valve opening that is available for blood flow
- Patients with severe AS have an EOA of ≤ 1cm$^2$

**Mean Pressure Gradient (MPG)**

- The average pressure across the aortic valve between the left ventricle and aorta
- Patients with severe AS have MPG ≥ 40 mmHg




*Follow-up Echo Core Lab Analysis

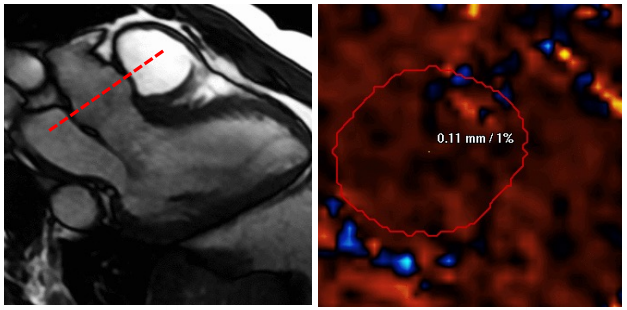
Waggoner T. "DurAVR® Biomimetic Transcatheter Heart Valve: Early Feasibility Study (EFS) Update". Oral Presentation at: CRT Conference, March 2024; Washington, USA.

# DurAVR® is the first aortic valve to restore normal aortic flow

**When compared to a healthy aortic valve, DurAVR® THV showed no significant difference in flow (p>0.05)**

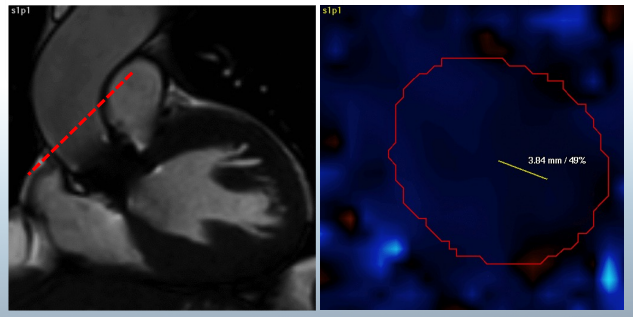
FD = Flow Displacement
FRR = Flow Reversal Ratio

**Healthy Aortic Valve**




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

**Post DurAVR® THV**



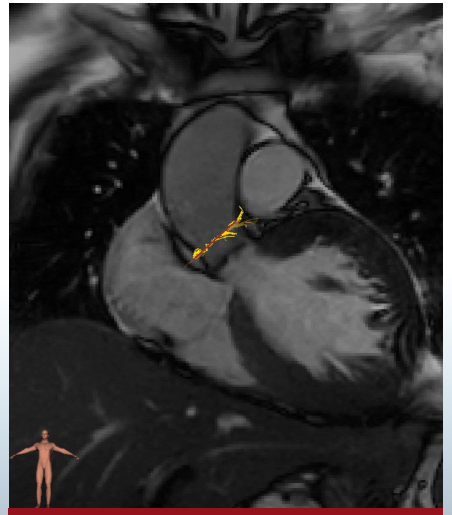

**FD = 14%**
**FRR = 4%**
(n=5)

Courtesy of Dr. Pankaj Garg, Norwich University Hospital (UK)

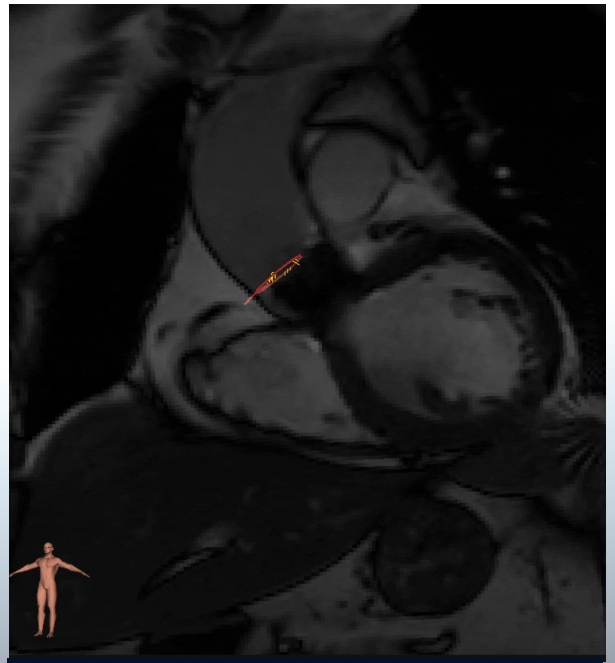
# LAMINAR FLOW – A THERAPEUTIC TARGET


resistance. Pilot data are now emerging from first-in-human studies that assessed the DurAVR valve, which incorporates a large length-to-diameter ratio with a wide effective valve area and a 3D single-piece leaflet geometry[79,80]. Early data suggest that, after implantation of the DurAVR valve in patients with aortic valve disease, aortic flow patterns (in terms of flow eccentricity measured by SFD and vortical flow measured by sFRR) were restored to those seen in healthy control individuals. This improvement in haemodynamics has implications both for the longevity of the valve and for the prevention of aortic root dilatation owing to eccentric aberrant flow in the ascending aorta. The emergence of these novel transcatheter aortic valves provides a less invasive treatment option, which might even be suited to younger cohorts when their safety and longevity have been tested in medium-to-long-term outcome studies.

## 4D Flow pre and post DurAVR®



Pre DurAVR®

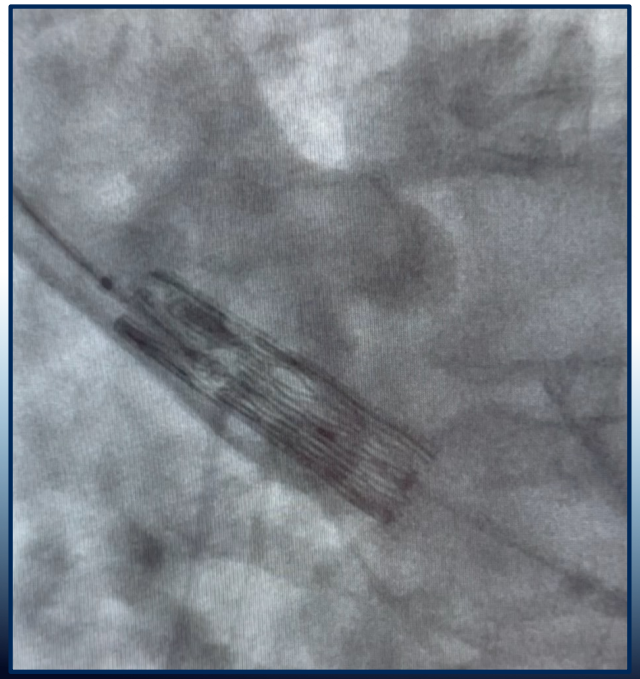


Post DurAVR®

Garg P, Markl M, Sathananthan J, Sellers SL, Meduri C, Cavalcante J. "Restoration of flow in the aorta: a novel therapeutic target in aortic valve intervention". Nat Rev Cardiol. 2023 Oct 25. doi: 10.1038/s41569-023-00943-6.

# Easy to Deliver, 100% Precise Placement and Implant Success

**No PVL reported at 30-days**



| EFS 30 Day Events[1] | N = 15 |
|---|---|
| **Primary Safety Endpoints** | |
| All-cause mortality or disabling stroke | 0 (0) |
| **Secondary Safety Endpoints** | |
| All-cause mortality | 0 (0) |
| Disabling Stroke | 0 (0) |
| VARC-3 type 2-4 bleeding | 0 (0) |
| Major vascular or structural heart complications | 0 (0) |
| Acute Kidney Injury (AKI) Stage 3 or 4 | 0 (0) |
| Moderate or severe aortic regurgitation | 0 (0) |
| New permanent pacemaker due to procedure-related conduction abnormalities (*) | 1 (6.7) |
| Surgery or intervention related to the device, including aortic valve reintervention | 0 (0) |
| | Data presented as n (%) |

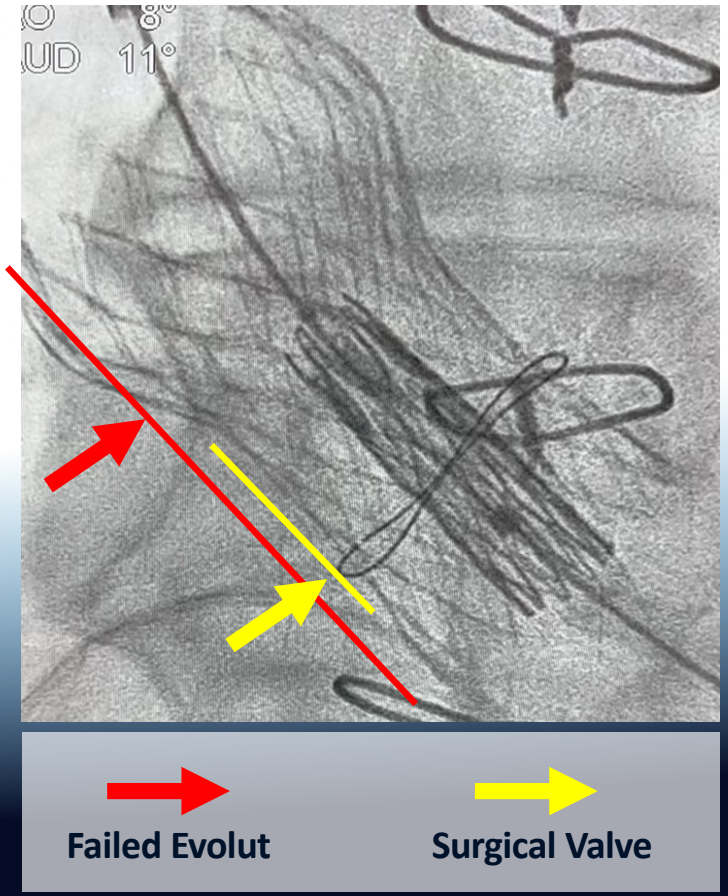
***(*) Subject with pre-existing significant conduction abnormalities with prolonged QRS***

1. Meduri C. DurAVR® Biomimetic Transcatheter Heart Valve: Early Feasibility and First-in-Human Trial Update. Oral presentation at: EuroPCR Conference; May 2024; Paris, France.

# DurAVR® Valve in Valve in Valve (ViViV)

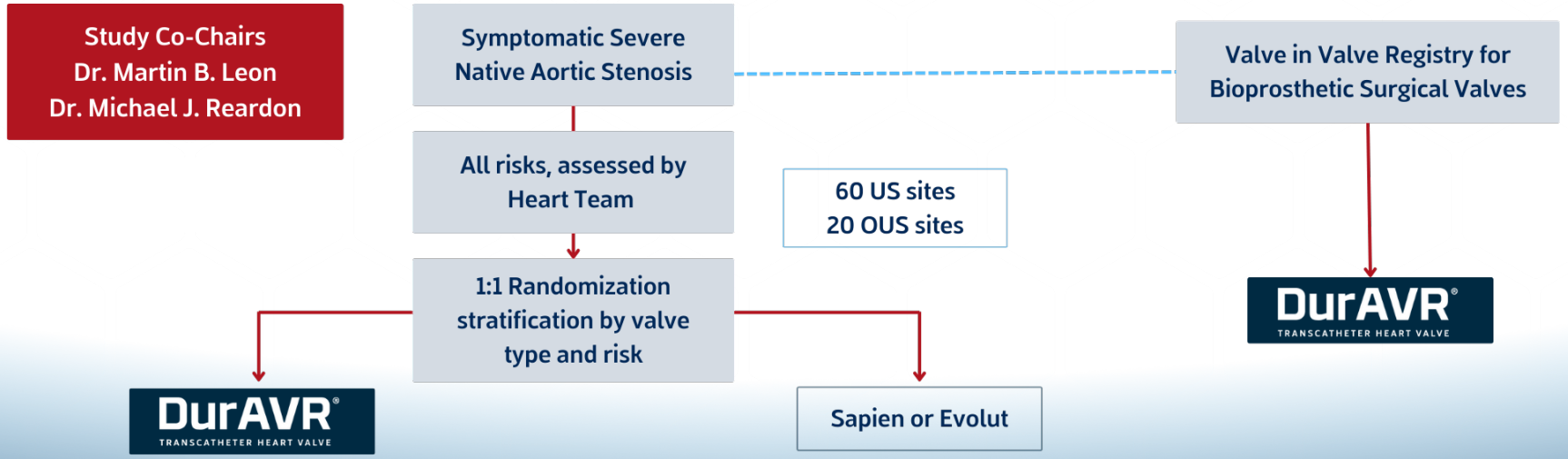
- 77-year-old male, too high risk for repeat surgery with failure of his valve in valve
- First surgical valve went in with mediocre hemodynamics and eventually failed
- A self expanding TAVR was placed in it (currently believed to be best in class for ViV) and it also provided mediocre hemodynamics
- Patient unsuitable for surgery and left with no reasonable alternatives. DurAVR® proposed as compassionate use and only option for the patient. Swedish FDA agreed it was only option and approved its usage

| Date | Vmax ao | MPG mmHg | DVI |
|---|---|---|---|
| 2011 Surgical Valve | 3.1 | 23 | 0.4 |
| 2018 Evolut in Surgical Valve | 3.7 | 31 | 0.34 |
| 2024 Max stress | 4.0 | 41 | 0.15 |
| **Post DurAVR®** | **3.0** | **20** | **0.33–0.40** |



## DurAVR® PIVOTAL STUDY (PHASE 3)

# The First All Risk Head-to-Head TAVR Registration Trial




Follow-up: 1 month, 1 year, annually through 10 years

**Proposed Sub-studies:**
- Flow dynamics
- CT sub-study (HALT, RLM)
- Health Economics

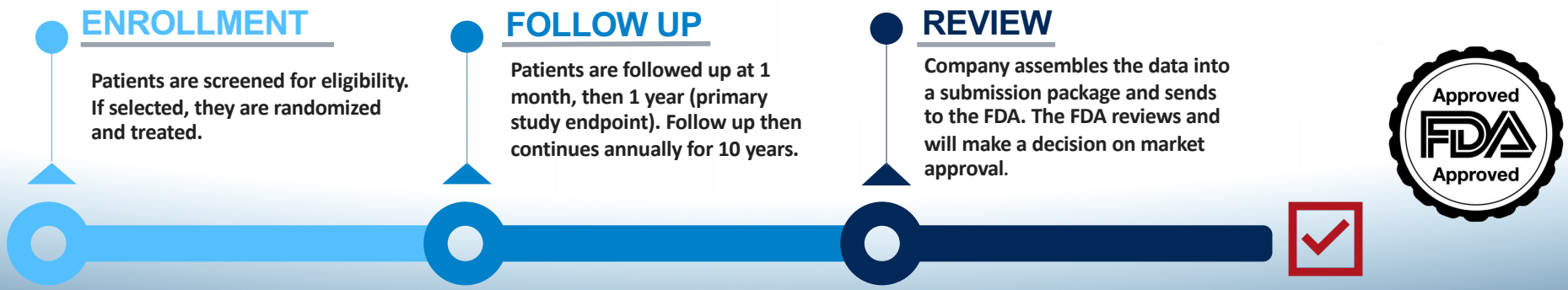
**Primary Endpoint (at 1 year)**
Non-Inferiority composite All-cause mortality, stroke, or hospitalization

**Secondary Endpoint**
Hemodynamic Superiority at 30 day/1 year

**Primary Endpoint (at 1 year)**
Non-Inferiority composite All-cause mortality, stroke, or hospitalization against PG

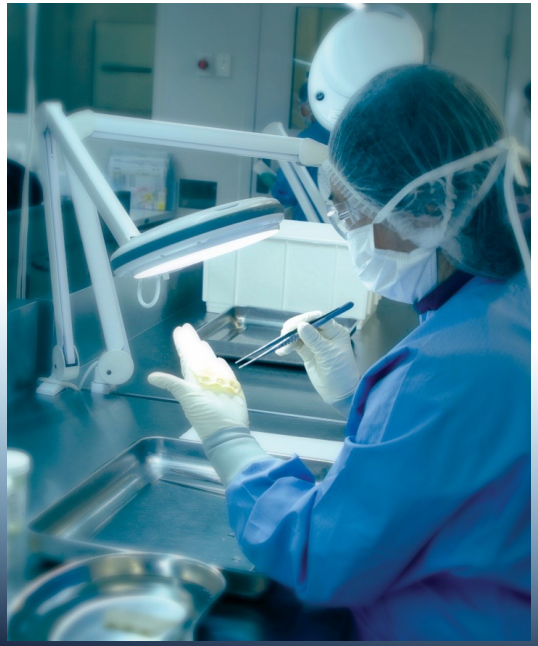
# Biomimetic outcomes are driving enthusiasm, the trial is expected to enroll quickly

**Anteris will request continued access for DurAVR® with the FDA**




MANUFACTURING

# ADAPT® tissue engineering (AU), DurAVR® assembly (US)

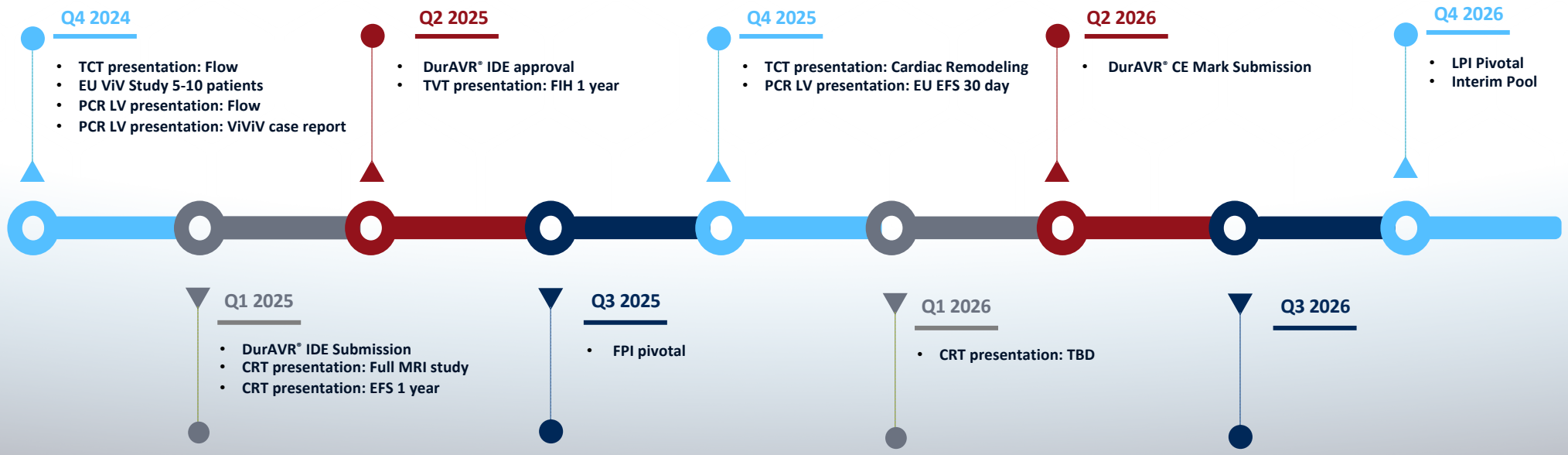


Malaga, WA, Australia

- **ADAPT® : multi-step, anti-calcification, tissue engineering process**
- **Transforms animal tissue into a durable bio-scaffold (intended to mimic human tissue and mitigate structural valve deterioration)**
- **Single-piece of shaped ADAPT® tissue attached to a stent via sutures**
- **Valve sterilized and packaged for use**

Minneapolis, USA

# Anticipated Milestones



# Anticipated Next Steps


- Seek FDA approval for global pivotal trial (US, EU, AU, ~80 sites)
- Pivotal trial patient recruitment commences
- FDA submission commences (modular approach)
- Monthly discussions with FDA
- Ongoing pre-market commercialization activities
- Ongoing discussions with potential partners
- Pivotal trial completion (incl. 1-year follow up)
- FDA submission complete
- FDA approval and commercialization if approved