

# Investor Presentation

May 2024





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02 R&D Innovation

Future Prospects

03



# 01 Global Expansion

### "Intelligently Manufactured in China" Valve Products Go Global



### Comprehensive Solutions for Structural Heart Disease

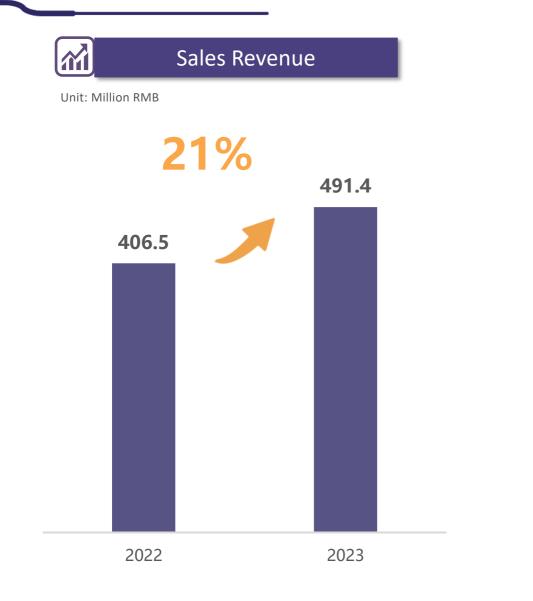
- All series of "China Intelligently Manufactured " valves have been introduced to more than 50 countries and regions worldwide, including Asia, Europe, South America
- A complete product pipeline covering all four heart valves, namely TAVR, TPVR, TMVR and TTVR, as well as hypertrophic cardiomyopathy, hypertensive renal denervation (RDN) therapy and relevant accessory products

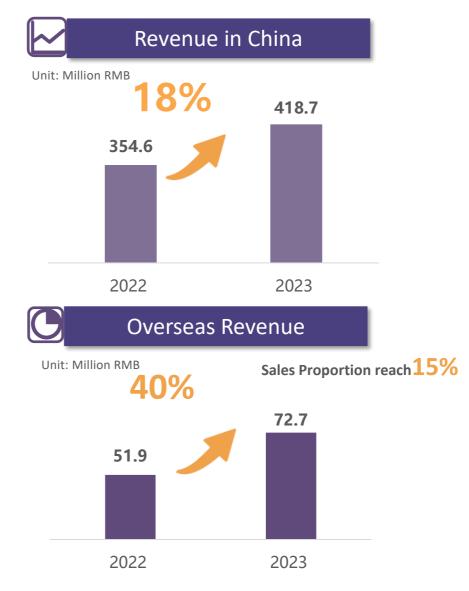




### Sales Revenue Continued to Grow, Overseas Business Performed Strongly







### **Globalization Strategy**



Global professional sales & marketing teams, supported by a robust international supply chain system

Rigorous production and quality management systems aligned with global standards from the U.S., the EU, and China

Excellent global clinical and registration capability, bolstering efforts to expand global presence



- **01** Advance diligently in the field of structural heart disease to address clinical pain points with ground-breaking innovations
- **02** Three R&D centers in China, the U. S. and Israel to ensure continuous innovation transformation
- Comprehensive global IP portfoliospanning across China, the U.S., Europeetc.

### **International IP Layout and Global Marketing**



**IP Portfolio** 

### Leading in IP Quality and Quantity

- As of April 30, , a total of 863 patents and patents under applications, including 707 invention patents, of which 432 are authorized invention patents
- IP covers China, U.S., Europe etc., of which 80% are invention patents

### In-depth Protection in Key Technology

 Detailed IP protection in key technology such as latest dry-tissue, balloon expandable valve, anti-PVL technology

### **Comprehensive Risk Management**

 dynamic and in-depth assessment and analysis management of business risks related to intellectual property In the whole life cycle of products

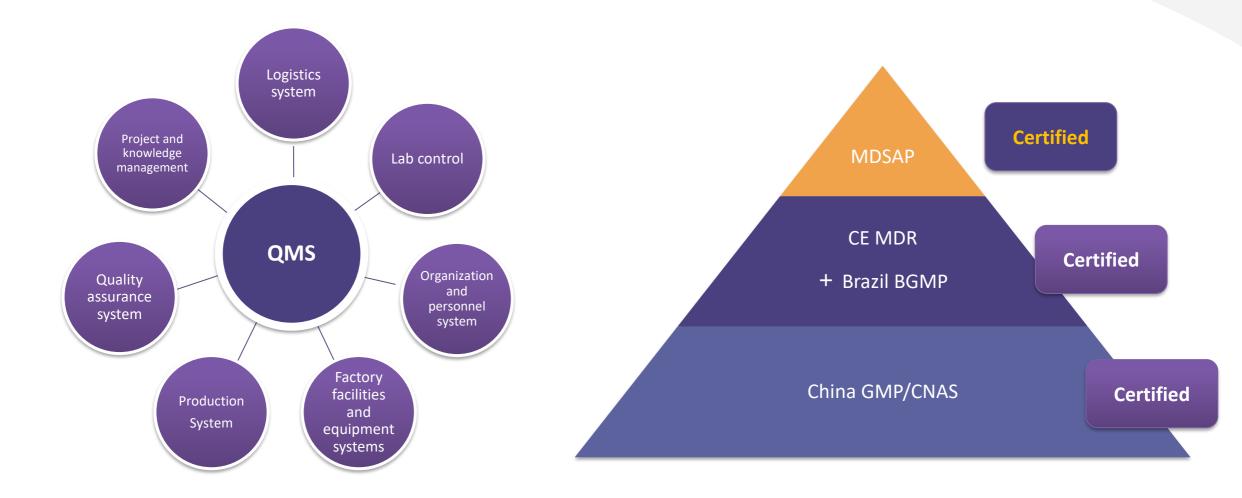




Appointed Shakeel Osman as the head of the International Congenital Heart Disease Department and leading the pulmonary valve business globally (except Chinese mainland)

### **Global Quality Management System Continuously Improve Production Efficiency**







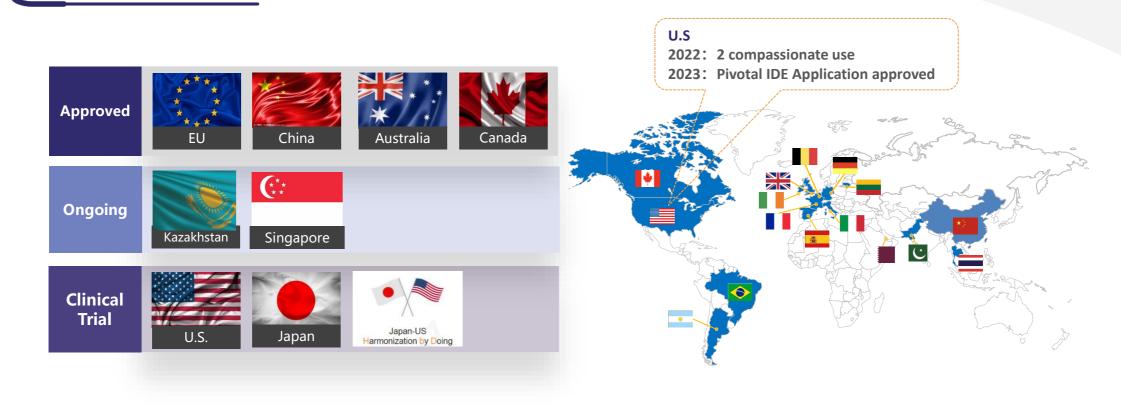


## **VenusP-Valve**

Transcatheter pulmonary valve replacement (TPVR)

### **VenusP-Valve: Global Business Grow Steadily**

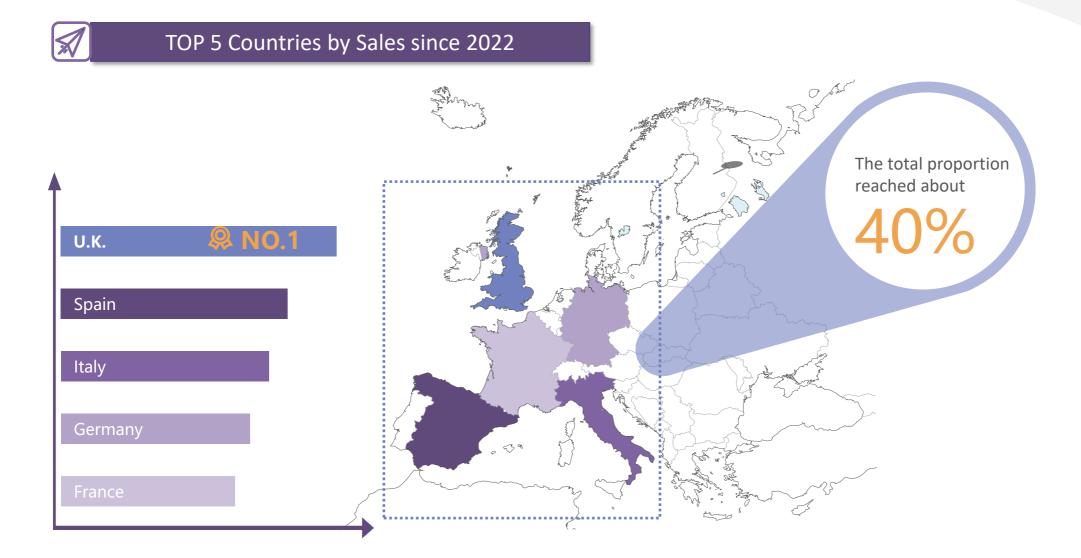






## **VenusP-Valve: Recognized by Mainstream Markets**



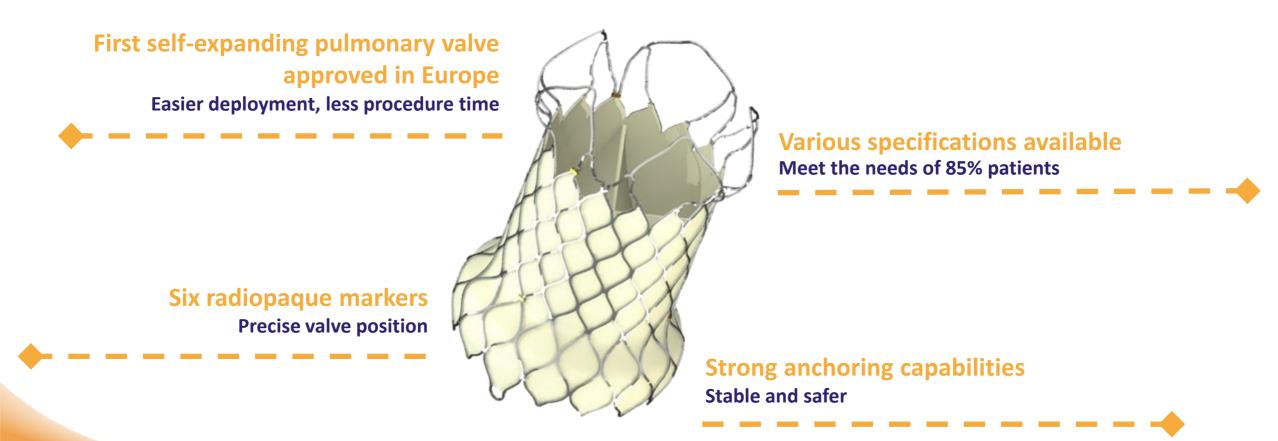


## VenusP-Valve: Clinical Study in the U.S. about to Begin



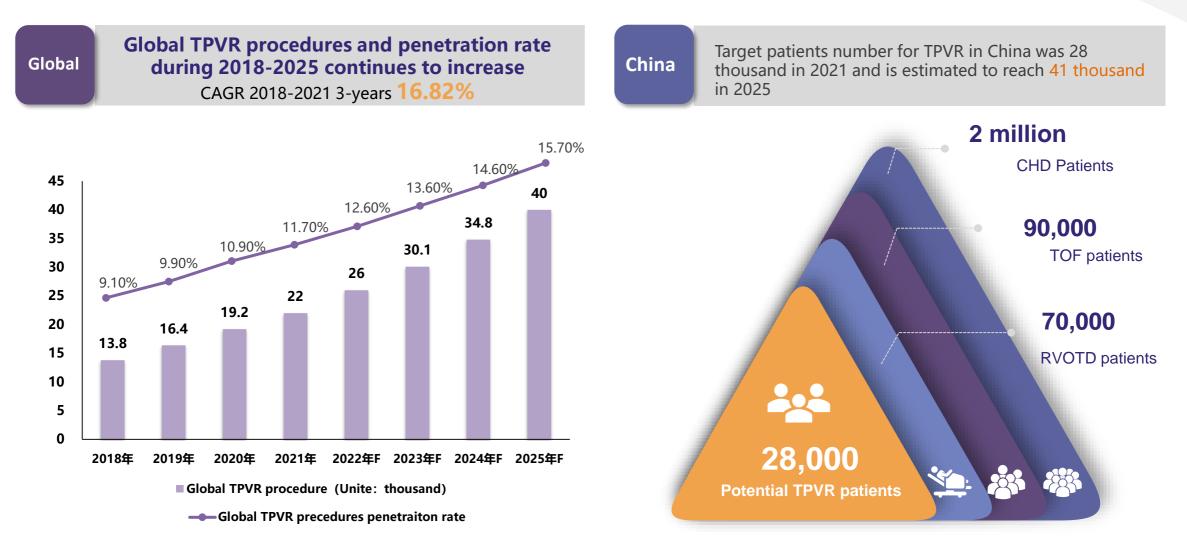
### The First China-made Valve Product Obtained Approval from FDA for IDE Study

- Obtained FDA Investigational Device Exemption (IDE) approval in July 2023 and pivotal clinical study about to initiate
- The clinical study is expected to enroll 60 patients In U.S. and Japan



### Wide Market of TPVR







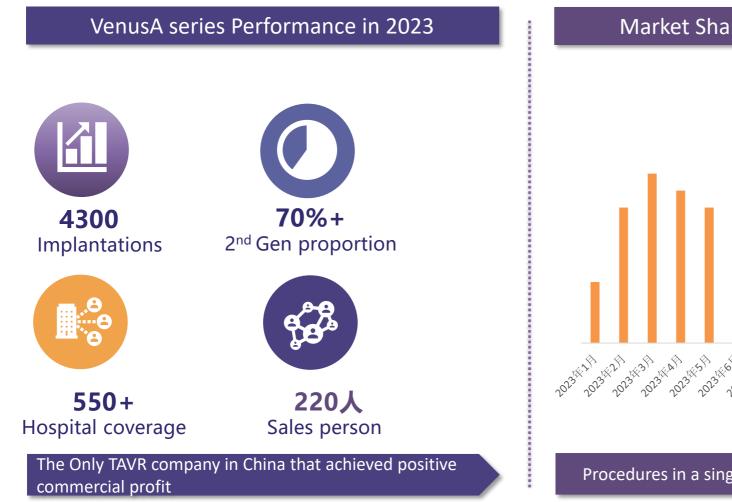


## **VenusA Series**

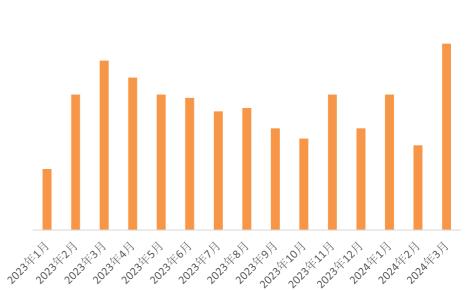
Transcatheter Aortic Valve Replacement (TAVR)

## TAVR in China: Profitability Strategy Paid off





### Market Share Continues to be No.1

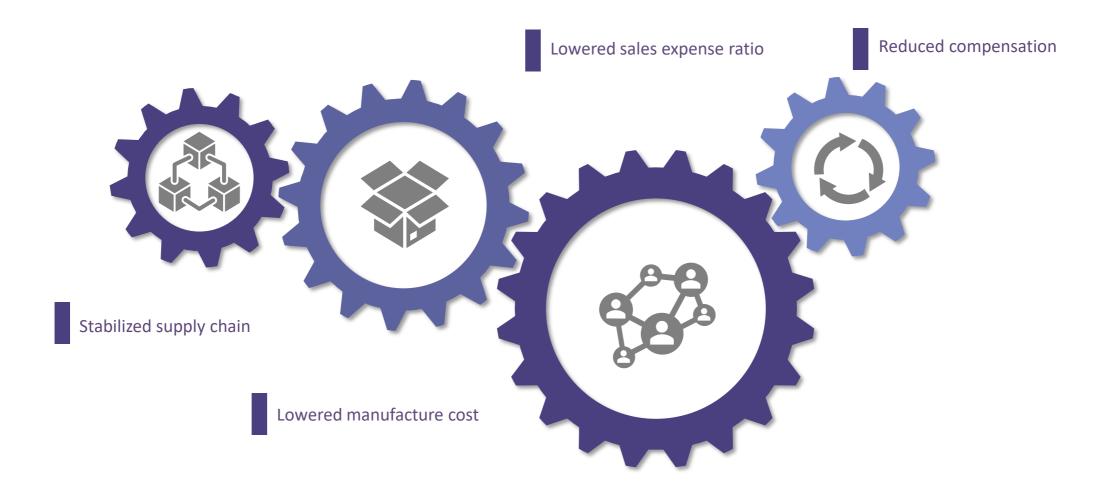


Procedures in a single month in 2023 hit a record high

## **Commercial Profitability Improved**



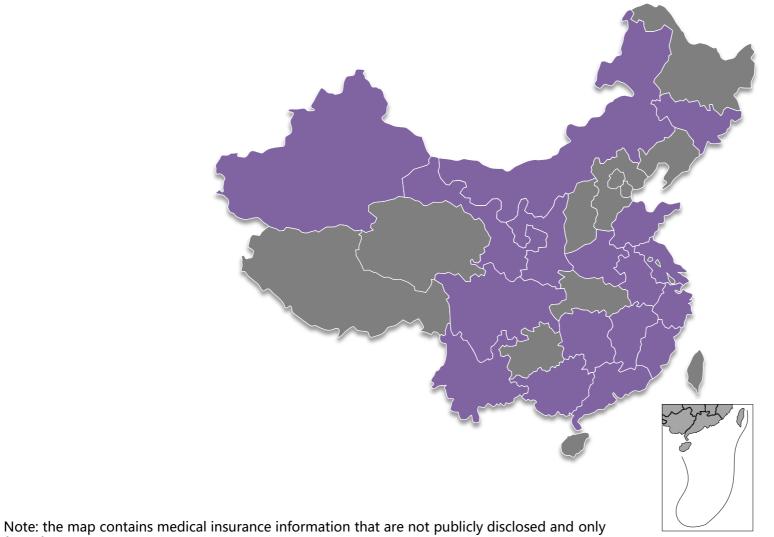
### 2023 Achieved about 47 million RMB Commercial Profit



## **Access for TAVR Promoted**



## TAVR Medical Insurance Coverage Continued to Increase in 2023



for reference.



# 02 R&D Innovation

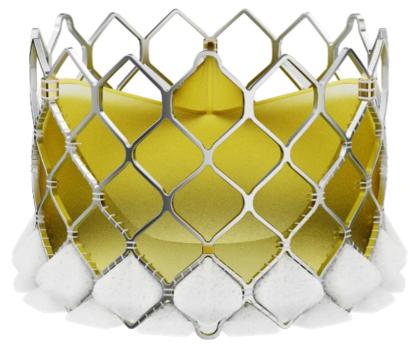




	Products		Pre Clinical	<b>Clinical Trials</b>	Registration	Marketed			
	TAVR	VenusA series	Approved in 10 countries including China, Asia-Pacific and Latin America				•		
Aortic Valve		Venus-Vitae	Preparing Pivotal Study		Approved in Arg	gentina and Chile			
		Venus-PowerX	Preparing Pivotal Study		Approved in Arg	entina and Chile			
		Valve for regurgitation	Animal Study						
Pulmonary Valve	TPVR	VenusP-Valve	Approved in 56 European, A	sia-Pacific and South American	countries; Preparing US P	ivotal study	•		
Mitral Valve	TMVR	Cardiovalve	EFS				Global progress		
Tricuspid Valve	TTVR	Cardiovalve	Pivotal Study				China progress		
Structural Heart	PIMSRA	Liwen RF	Completed Enrollment of	Pivotal Study					
Platform Technology	RDN	Echomplish Platform	Animal Study						
Accessories	3 <sup>nd</sup> generation catheter sheath	G Sheath	Approved in China						
	Balloon expandable sheath	TAVO	Approved in China				•		







### Feature & Clinical Progress

- Balloon-expandable valve design
- Anti-calcification treated dry-tissue powered by Venus
  - Endura
- Patented lock-wire technology
- Steerable control, Commissures alignment, Coaxial rotation
- Adaptive active annular sealing technology
- Approved in Argentina in Dec 2022
- Approved in Chile in Oct 2023



#### Significant Improvement of Hemodynamic Performance

A

в

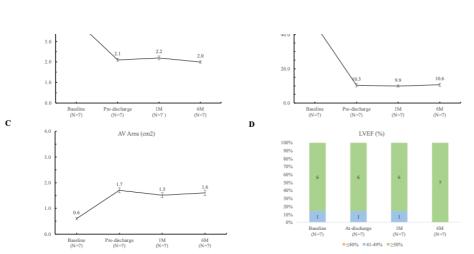


Figure 2. significant improvement in AV peak velocity (A), AV mean gradient (B), AV area (C) and LVEF (D) at 6-month follow-up. Error bars represent 95% CI. AV=aortic valve, LVEF=left ventricular ejection fraction.

#### Significant Improvement of Heart Function

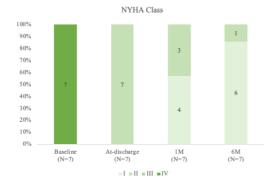


Figure 3. significant improvement in NYHA class heart function at 6-month follow-up. NYHA=New York Heart Association.

#### **Occurrence of Averse Events Post-procedure**

Table 3. Occurrence of Averse Events Post-procedure (N=7)

	Baseline	Pre-discharge	1 Month	6 Months
Mortaliy	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Strok	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Heart failure re-hospitalization	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Reintervention	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Acute kidney injury	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Major bleeding	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Major vascular/access/cardiac structure related complication	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Moderate or greater aortic regurgitation	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
РРМІ	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
LBBB	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)

PPMI=Permanent Pacemaker Implantation,

LBBB=Left Bundle Branch Block.

- Procedural Technical Success: 100%
- No Death, No Stroke and No Reintervention
- Significant Improvement of Hemodynamic Performance

## **Venus-Vitae Global Strategy**

### Global Clinical & Registration Strategy

- Global pivotal clinical study is expected to begin in 2H2024
- Support both CE Mark and China NMPA approval



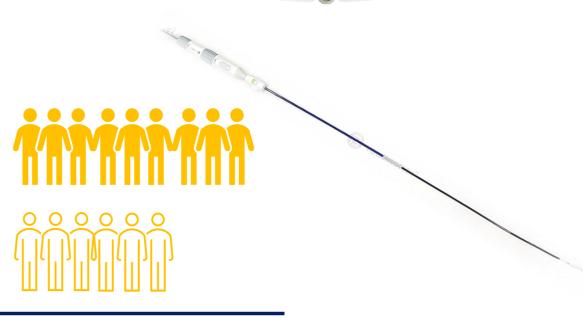
### Vitae Global

- Europe ≈60%
- ≻ China ≈40%

**Global Enrollment 150** 









## **Venus-PowerX**

### Feature & Clinical Progress

- Self-expanding TAVR
- Anti-calcification treated dry-tissue powered by Venus Endura
- Pre-mounted, less preoperative loading time
- Active anti-PVL technology
- Fully-released, 100% retrievable
- EFS completed and in follow-up status
- Approved in Argentina in May 2023
- Approved in Chile in Oct 2023





## **Venus-PowerX FIM Clinical Results**

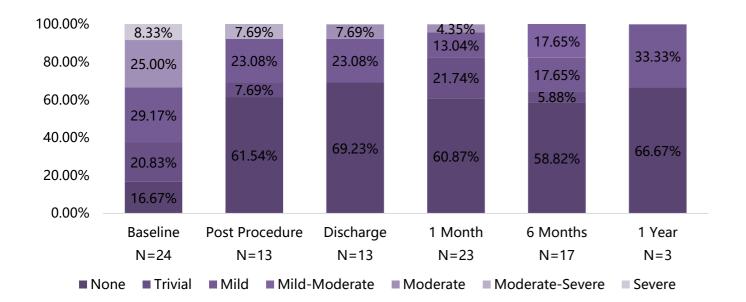


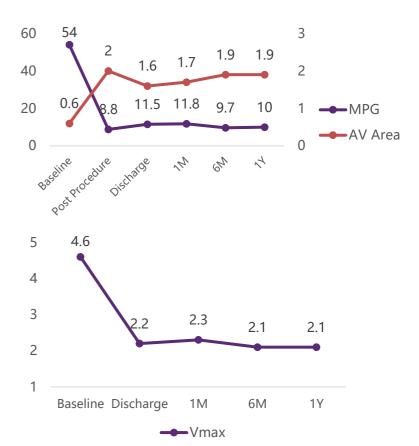
- No all-cause mortality, all-cause stroke, or valve reintervention
- VARC-3 technical success at exit from operation room: 95.8%
- VARC-3 device success at 30 days: 87%

	Overall	_	At 30 Days
	(n = 24)		(n = 23)
Procedural variables		VARC-3 device success at 30 days <sup>a</sup>	20 (87.0)
Transfemoral access	24 (100.0)	Early safety at 30 days <sup>b</sup>	17 (73.9) <sup>c</sup>
Pre-dilatation	20 (83.3)	Moderate PVL	1 (4.3) <sup>d</sup>
Post-dilatation	10 (41.7)	Aortic peak velocity ≥3 m/s	1 (4.3)
Recapture at partial deployment	8 (33.3)	Aortic mean gradient ≥20 mmHg	2 (8.7)
Recapture at 100% full deployment	2 (8.3)	All-cause death	0 (0.0)
VARC-3 technical success <sup>a</sup>	23 (95.8)	All stroke	0 (0.0)
Successful implantation	24 (100.0)	Myocardial infarction	0 (0.0)
Single valve implanted in correct position	24 (100.0)	Cardiovascular hospitalizations	0 (0.0)
Conversion to open heart surgery	0 (0.0)	VARC type ≥2 bleeding	1 (4.3)
Coronary obstruction	0 (0.0)	Major vascular complications	1 (4.3)
New pericardial effusion	0 (0.0)	Major access-related complications	0 (0.0)
Major vascular complications	1 (4.2)	Acute kidney injury	0 (0.0)
Major access-related complications	0 (0.0)	Clinically significant valve thrombosis	0 (0.0)
Procedural death	0 (0.0)	New permanent pacemaker implantation	4 (17.4) <sup>e</sup>



- Valve function improved significantly
- 30-days follow-up: >95% ≤ mild AR; 6-month and 1-year follow-up: "0" ≥moderate AR





## **Venus-PowerX Global Strategy**



### Global Clinical & Registration Strategy

- EFS completed in Jan 2024, with patients in follow-up
- Global pivotal clinical study is expected to begin in 2H 2024



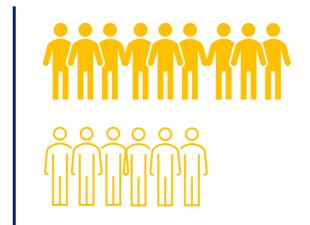
### **PowerX Global**

- Europe ≈40%
- China ≈60%

150

Global Enrollment









Feature & Clinical Progress

- Fits both MR & TR
- Dual frame self-expanding nitinol, less PVL
- Low ventricular profile, less risk of LVOT obstruction
- Transfemoral-transseptal approach, less damage
  - comparing with transapical approach
- Target CE pivotal clinical study for TR has been

initiated in Nov 2022

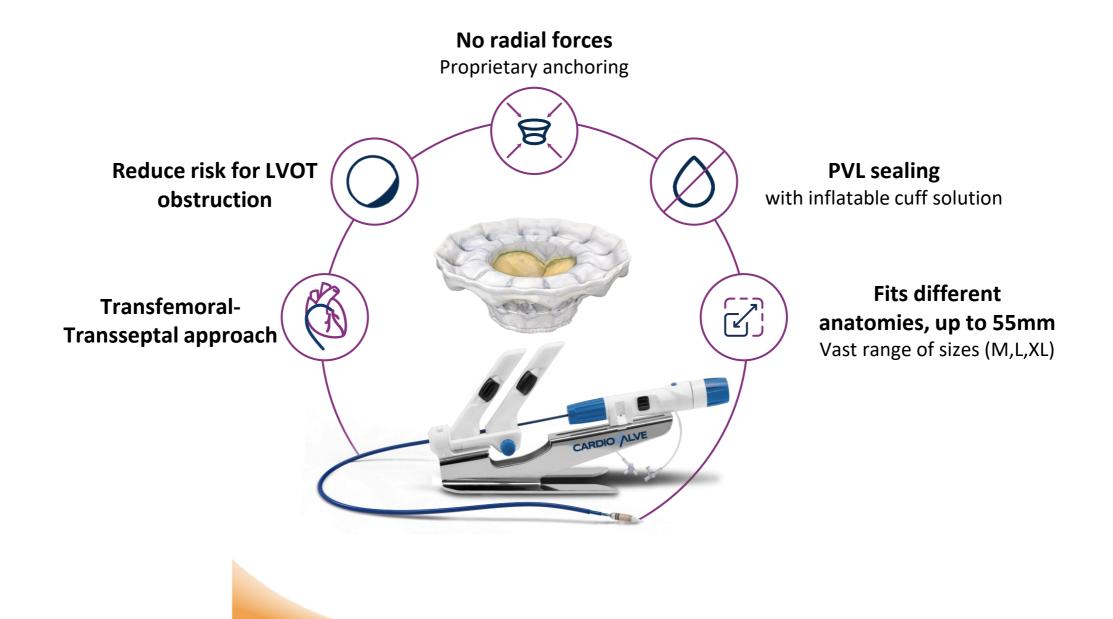


CARDIO ALVE



## **Cardiovalve for Mitral and Tricuspid**





## **Cardiovalve Tricuspid Compassionate Use Data**



- All patients are functional severe TR; inoperable and suboptimal TEER candidates
- High technical success for valve implantation

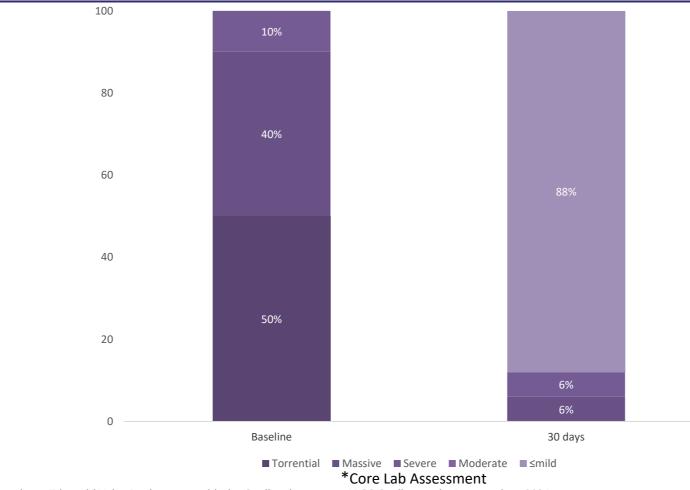
Baseline Characteristics (N=20)				
Age (Years)		79±6	TR Etiology:	100% FTR
NYHA Ⅲ/Ⅳ (%)		12 (60)	Severe TR (%)	2 (10)
Atrial Fibrillation(%)		19 (95)	Massive (%) Torrential (%)	8 (40) 10 (50)
Prior cardiovascular surgery (%)		6 (30)	LVEF (%)	49
Prior HF Hospitalizations in past year(%)		10(50)	<b>GRF</b> <45 (%)	8 (40)
Procedure Success				
Technical Success (%)		90% (18)		
Procedure Time (min) (Avg; Min, Ma	x)		83 (30,125)	
30-Day Clinical Outcome	e (N=20)			
*Mortality	10% (2)		Reintervention	5% (1)
PPM	10% (2)		Bleeding	20% (4)
<b>HF re-hospitalizaitons</b> 5% (1) **None of the death was device related			Dialysis	5% (1)

Refrerece: Transcatheter Tricuspid Valve Replacement with the Cardiovalve system, JACC Cardiovascular Interventions 2024

## **Cardiovalve Tricuspid Compassionate Use Data**



- Pre-operation: 100% patients ≥ Severe Regurgitation
- 30-Days follow-up: 95% of patients TR reduced with TR grade ≤1



Reference: Transcatheter Tricuspid Valve Replacement with the Cardiovalve system, JACC Cardiovascular Interventions 2024

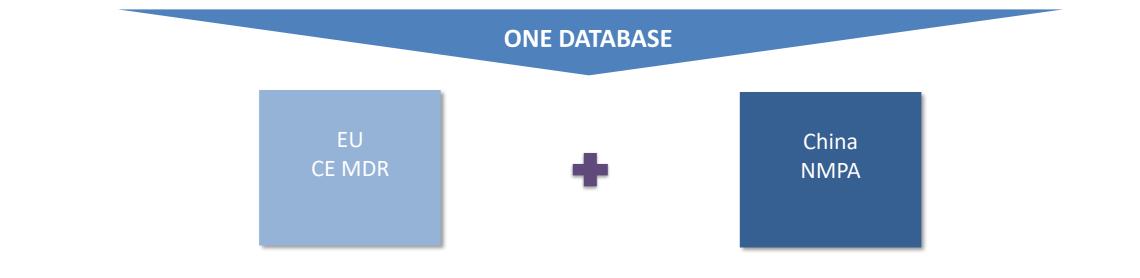
## **Cardiovalve Global Strategy**





### TR – Global Strategy

- TARGET CE pivotal study has been initiated in Nov 2022
- Multi-Country including Europe and Canada
- As of April 30, enrolled 70+ patients
- Support both CE Mark and China NMPA approval





## **TARGET Study Sites**





## **Epidemiology of Tricuspid Valve Diseases**



Tricuspid valve is regarded as "the forgotten valve", indicating huge patient number and market size

It's estimated that number of patients with tricuspid valve regurgitation worldwide will achieve 60 million by year 2030, with an incidence case of 200-300 thousand in EU, US respectively.

Tricuspid valve regurgitation has high incidence rate and severe patients' mortality rate is 36% in 1 year and 48% in 5 years.

The market value of tricuspid valve therapies expected to reach USD \$ 10 billion in 2030

	1,600,000	• TR patients			
	250,000	<ul> <li>Incidence of TR</li> </ul>			
	50,000	<ul> <li>Surgery of MR</li> </ul>			
	<8,000	<ul> <li>Surgery of TR</li> </ul>			
90% Repair					

Sources: 1. Prevalence of moderate-to-severe TR suitable for percutaneous intervention in TTE patients; <u>Z H Teoh</u>, <u>J Roy</u>, <u>J Reiken</u>, <u>M Papitsas</u>, <u>J Byrne</u>, and <u>M J Monaghan</u>; Published online 2018 Oct 29. doi: <u>10.1530/ERP-18-0018</u>; National Library of Medicine 2. Argarwal et al. Circ Cardiovasc Interv 2009;2:565-573

3.Stuge O, Liddicoat J. J Thorac Cardiovasc Surg. 2006 Dec;132(6):1258-61

## **RDN Ultrasound Ablation**



Venus Medtech formed a joint venture company with Healium Medical Ltd. to introduce next-generation ultrasound ablation

technology. The product is under animal experiment

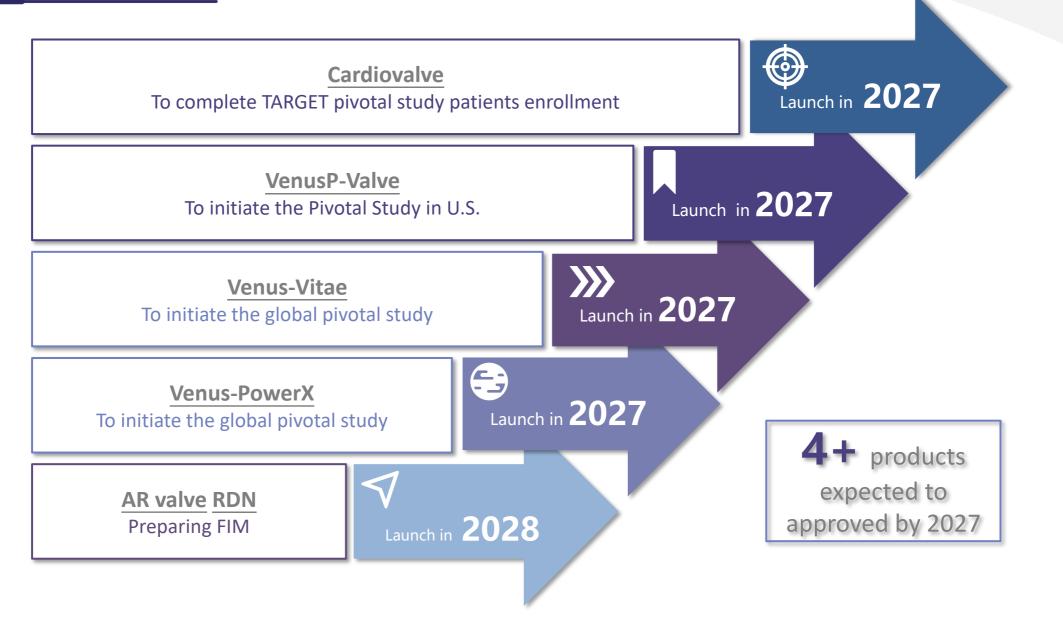












## **Outlook of Overseas Sales**



Overseas sales proportion will increase with innovative products enter harvest period



## **Our Mission & Vision**

## To be a global leader in structural heart



# Thanks!