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## Jenscare Scientific Co., Ltd. 寧波健世科技股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 9877)

# VOLUNTARY ANNOUNCEMENT THE SIX-MONTH CLINICAL FOLLOW-UP RESULTS FOR LARGE ANNULUS PATIENTS OF LUX-VALVE PLUS TRINITY STUDY AND CLINICAL APPLICATION RESULTS FOR LARGE ANNULUS PATIENTS OF KEN-VALVE RELEASED AT PCR LONDON VALVES 2025, DEMONSTRATING LARGE SIZE ADVANTAGES WITH PRODUCT UNIQUENESS

This announcement is made by Jenscare Scientific Co., Ltd. (the "Company", together with its subsidiaries, the "Group") on a voluntary basis to provide the shareholders and potential investors of the Company with updated data in relation to the latest business and product portfolio development of the Group.

The board ("Board") of directors ("Directors") of the Company is pleased to announce that recently, the six-month clinical follow-up results for patients with large annulus of the global multi-center clinical trial of the LuX-Valve Plus transcatheter tricuspid valve replacement ("TRINITY") and the one-year clinical follow-up results of Ken-Valve in patients with large annulus were released at PCR London Valves 2025, demonstrating large size advantages of the Company's products, which are expected to address a broad range of unmet clinical needs.

# LUX-VALVE PLUS TRINITY STUDY: SIX-MONTH FOLLOW-UP RESULTS IN PATIENTS WITH LARGE ANNULUS

### - Released by Prof. Thomas Modine, CHU de Bordeaux-Haut-Leveque, France

TRINITY is a global prospective, multicenter, single-arm clinical trial, which primarily evaluates the safety and efficacy of LuX-Valve Plus in application on patients with severe tricuspid regurgitation ("TR") and high surgical risk. The study enrolled 161 patients from 20 centers around the world, among which, 18 centers were from France, Germany, Spain, Denmark, and the United Kingdom.

Patients with severe tricuspid regurgitation often have concomitant dilation of right ventricular and tricuspid annulus, which is one of the primary factors increasing the difficulty of tricuspid regurgitation intervention therapy. For patients with large annulus, there are very few safe and effective clinical treatment options, indicating a significant unmet clinical need. LuX-Valve Plus has seven valve sizes ranging from 40mm to 70mm. In the TRINITY study, over 75% of patients used valve sizes of 55mm, 60mm, 65mm, and 70mm. The average age of these patients was 77 and the average Tri-Score was as high as 13.5%; 10.7% of patients exhibited Severe TR, 47.1% exhibited Massive TR, and 42.2% exhibited Torrential TR.

The six-month clinical follow-up results show the excellent efficacy and safety of LuX-Valve Plus in patients with large annulus.

### The clinical results showed:

- (1) The device success rate of the FAS ("**full analysis set**") + Roll-in group was about 97%, among which the success rate of LAP<sup>a</sup> is as high as 97.5%; and
- (2) The average device operation time for the FAS + Roll-in group was 42.03±20.27 minutes, among which the shortest device operation time for LAP was only 11 minutes.
  - Note a: Large annulus patients (LAP) group are defined as patients using valve sizes of 55mm, 60mm, 65mm and 70mm:

### The efficacy results showed:

- (1) In terms of improvement in the tricuspid regurgitation grade, 94.4% of the patients in the FAS + Roll-in group showed no above moderate regurgitation, and 93.5% of the LAP showed no above moderate regurgitation;
- (2) In terms of New York Heart Association cardiac function improvement, 90.9% of patients in the FAS + Roll-in group achieved postoperative cardiac function class I/II, among which, 88.8% of LAP had their postoperative cardiac function improved to class I/II; and
- (3) In terms of quality of life, patients in the FAS + Roll-in group improved their Kansas City Cardiomyopathy Questionnaire scores, on average, by approximately 19 points, with an average improvement of approximately 18 points for LAP; in addition, the average improvement in 6-minute walking distance for the patients in the FAS + Roll-in group was approximately 28 meters, with an average improvement of approximately 29 meters for LAP.

The safety results showed:

| Clinical Event Committee (CEC) – adjudicated            | FAS + Roll-in | LAP      |
|---|---------------|----------|
| Composite Events at Six-Month                           | (N=161)       | (N=121)  |
| Cardiovascular mortality                                | 3.7%(6)       | 4.1%(5)  |
| Myocardial infarction                                   | 0             | 0        |
| Strokes   | 0.6%(1)       | 0.8%(1)  |
| New onset renal failure                                 | 1.2%(2)       | 1.7%(2)  |
| Severe bleeding (includes fatal, life-threatening and   |               |          |
| extensive bleeding as defined by MVARC)                 | 5.0%(8)       | 5.8%(7)  |
| Non-selective tricuspid valve surgery/intervention post |               |          |
| procedure   | 2.5%(4)       | 3.3%(4)  |
| Major cardiac structural complications                  | 3.1%(5)       | 2.5%(3)  |
| Major access site and vascular complications            | 0             | 0        |
| Device-related pulmonary embolism                       | 0             | 0        |
| New pacemaker implantation due to AV block              | 8.7%(14)      | 9.1%(11) |
| Composite Events Rate                                   | 19.9%         | 22.3%    |

Although the preoperative baseline data of large annulus patients showed more severity in terms of tricuspid regurgitation grade, surgical high risk degree, right ventricular function, right atrial volume, tricuspid annulus dilatation degree, etc., and had more complex anatomical structure, in terms of TRINITY study, the six-month clinical follow-up results for large annulus patients showed excellent safety and efficacy in the application of LuX-Valve Plus in large annulus patient, especially a significant decrease in tricuspid regurgitation grades, notable improvement in quality of life and a relatively low rate of composite adverse events for large annulus patients.

# KEN-VALVE: ONE-YEAR CLINICAL FOLLOW-UP RESULTS OF LARGE ANNULUS PATIENTS

### - Released by Prof. Anson Cheung, St Paul's Hospital, Canada

The study of Ken-Valve TAVR system is a prospective, multicenter, single-arm clinical trial, which primarily evaluates the safety and efficacy of Ken-Valve in application on patients with symptomatic aortic regurgitation (or combined with aortic stenosis) at high surgical risk, which enrolled 142 patients from 15 centers in China. The Ken-Valve offers six sizes ranging from 23mm to 33mm. In this study, over 45% of patients used valve sizes of 29mm, 31mm and 33mm. The average age of these patients reached 72 years and the average STS score reached 5.60%. Due to their challenging anatomical structures, patients with large annulus have very few safe and effective clinical treatment options, representing a significant unmet clinical need.

The results of this clinical study showed:

- (1) The device success rate for the full analysis set was 97.2%, with 93.8% for LAP<sup>b</sup>;
- (2) The average device operation time for the full analysis set was 8.70±8.85 minutes, with the average device operation time for LAP being 8.23±4.60 minutes.

*Note b:* Large annulus patients (LAP) group are defined as patients using valve sizes of 29mm, 31mm, and 33mm;

### The efficacy results showed:

- (1) In terms of improvement in the aortic regurgitation grade, one-year follow-up results demonstrated that patients across all valve sizes all had effective and durable improvement in regurgitation grade, among which, 100% of LAP had no above moderate regurgitation; and
- (2) In terms of New York Heart Association cardiac function improvement, one-year follow up results demonstrated that patients across all valve sizes had effective and durable improvement in cardiac function, among which, 96.7% of LAP achieved a postoperative cardiac function class I/II; and
- (3) In terms of quality of life, one-year follow-up results demonstrated that patients across all valve sizes had effective and durable improvement in quality of life, among which, LAP improved their EQ-5D scores, on average, by approximately 18 points; and
- (4) In terms of effective orifice area (EOA) and mean transvalvular pressure gradient, oneyear follow-up results of LAP demonstrated favorable valve function, with EOA and mean transvalvular pressure gradient maintaining stable levels.

The safety results showed:

|  | <b>Full Analysis</b> |                  |
|--|----------------------|------------------|
| Major Adverse Events at One Year                 | Set(N=142)           | <b>LAP(N=65)</b> |
| All-cause mortality                              | 5.63%(8)             | 4.62%(3)         |
| Permanent pacemaker implantation rate            | 14.08%(20)           | 16.92%(11)       |
| – III degree AV block                            | 8.45%(12)            | 9.23%(6)         |
| <ul> <li>Other types of arrhythmias</li> </ul>   | 5.63%(8)             | 7.69%(5)         |
| Severe bleeding                                  | 4.23%(6)             | 4.62%(3)         |
| Stroke   | 2.11%(3)             | 3.08%(2)         |
| Valve migration                                  | 2.11%(3)             | 4.62%(3)         |
| Conversion to surgery                            | 1.41%(2)             | 3.08%(2)         |
| Acute renal dysfunction                          | 0.70%(1)             | 1.54%(1)         |
| Needed for cardiopulmonary mechanical assistance | 0.70%(1)             | 1.54%(1)         |

Although the preoperative baseline data of LAP showed more severe aortic regurgitation grades, larger vena contra width and more severe annulus dilation, the one-year clinical follow-up results of Ken-Valve demonstrated that Ken-Valve still showed excellent safety and efficacy in the application, especially a significant decrease in aortic regurgitation grade, notable improvement in quality of life and a relatively low rate of adverse events for large annulus patients. The widespread use of Ken-Valve in LAP provides encouraging treatment options for patients with severe aortic regurgitation, potentially addressing a large unsatisfied clinical need.

Cautionary Statement as required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: There is no assurance that the Company will ultimately develop and market LuX-Valve Plus and/or commercialize Ken-Valve successfully. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By Order of the Board

Jenscare Scientific Co., Ltd.

Mr. PAN Fei

Executive Director and Chief Executive Officer

Hong Kong, November 20, 2025

As at the date of this announcement, the executive Director is Mr. PAN Fei; the non-executive Directors are Mr. LV Shiwen, Mr. TAN Ching, Mr. ZHENG Jiaqi, Ms. XIE Youpei and Mr. CHEN Xinxing; and the independent non-executive Directors are Dr. LIN Shoukang, Ms. DU Jiliu and Dr. MEI Lehe.