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 UPDATE ON RESULTS OF CLINICAL STUDIES OF THE COMPANY'S MULTI-PRODUCT PORTFOLIO ARE RELEASED AT TCT 2025 IN THE U.S., INCLUDING THE LUX-VALVE PLUS TRINITY STUDY, JENSCLIP CLINICAL STUDY, AND KEN-VALVE CLINICAL STUDY

Reference is made to the Company's announcement dated October 28, 2025 (the "**October 28 Announcement**"). 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 updates to the October 28 Announcement which is restated herein with updated information regarding the safety results indicated in underline.

The board ("**Board**") of directors ("**Directors**") of the Company is pleased to announce that recently, the 6-month clinical follow-up results of the global multicenter clinical trial of the LuX-Valve Plus transcatheter tricuspid valve replacement (the "**TRINITY**") and safety and efficacy evidence for the transjugular approach, the one-year follow-up results and application in challenging clinical cases of the JensClip transcatheter mitral valve repair (TMVr) system, as well as the one-year follow-up results and application in challenging clinical cases of the Ken-Valve transcatheter aortic valve replacement (TAVR), were released at the 2025 Transcatheter Cardiovascular Therapeutics conference (TCT 2025) in San Francisco, United States.

The 6-month Global Follow-Up Results of LuX-Valve Plus TRINITY Study

– 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 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 UK, and the average age of the patients was 77.

The results of this clinical study showed:

(1) The device success rate was about 97%; and

(2) The average device operation time was 41.60±19.62 minutes, with the shortest device operation time being only 11 minutes.

The efficacy results showed:

(1) In terms of improvement in the tricuspid regurgitation grade, 6-month outcomes demonstrated that 94.4% of patients had no above moderate regurgitation; and

(2) In terms of New York Heart Association cardiac function improvement, 6-month outcomes demonstrated that 90.9% of patients achieved postoperative cardiac function class I/II, respectively; and

(3) In terms of quality of life, 6-month outcomes demonstrated that patients improved their Kansas City Cardiomyopathy Questionnaire scores, on average, by approximately 19 points with an average improvement of approximately 39 meters in the six-minute walking distance.

The safety results showed:

Clinical Event Committee (CEC) – adjudicated Composite Events (FAS + Roll-in, N=161)	**At 6 month**
Cardiovascular mortality	6 (3.7%)
Myocardial infarction	0 (0.0%)
Strokes	1 (0.6%)
New onset renal failure	2 (1.2%)
Severe bleeding (includes fatal, life-threatening and extensive bleeding as defined by MVARC)	8 (5.0%)
Non-selective tricuspid valve surgery/intervention post procedure	4 (2.5%)
Major cardiac structural complications	5 (3.1%)
Major access site and vascular complications	0 (0.0%)
Device-related pulmonary embolism	0 (0.0%)
New pacemaker implantation due to AV block	14 (8.7%)
New pacemaker implantation due to AV block (Naive)	14 (11.9%)

The overall CEC-adjudicated composite events rate at 6 months of FAS + Roll-in group is 19.9%.

The 6-month clinical follow-up results of the TRINITY study demonstrated good safety and performance of LuX-Valve Plus, with continued improvement in the quality of patient's life and a stable, low rate of safety events compared to the 30-day follow-up results. The broad range of application of LuX-Valve Plus is providing an excellent treatment option, particularly for patients of annular dilation with severe tricuspid regurgitation, who have limited choices among current clinical treatments. In the TRINITY study, over 75% of enrolled patients received large-sized prostheses (55mm, 60mm, 65mm, and 70mm). Longer-term follow-up data and global clinical research findings for LuX-Valve Plus continue to be accumulated. Currently, the U.S. FDA-approved IDE-EFS for LuX-Valve Plus has completed full enrollment, achieving a 100% device success rate with excellent safety and efficacy outcomes. The FDA Pivotal Study is scheduled to commence imminently.

Meanwhile, evidence supporting the efficacy and safety of the transjugular approach for LuX-Valve Plus was also presented at the TCT conference. The advantages of the transjugular approach include a lower incidence of puncture site bleeding complications, reflecting superior safety indicators; shorter device operation time, demonstrating higher procedural efficiency; and a lower screening failure rate due to the anatomical structure of the jugular vein. Current data from the TRAVEL II and TRINITY studies show bleeding complication rates of 0% and 1.8% respectively, representing outstanding clinical outcomes.

One-Year Follow-Up Results of JensClip

– Released by Prof. Vinicius Esteves, University Hospitals in Cleveland, U.S.

The study of JensClip TMVr system is a prospective, multicenter, single-arm clinical trial, which primarily evaluates the safety and efficacy of JensClip in application on patients with symptomatic degenerative mitral regurgitation (DMR) at high surgical risk. The study enrolled 114 patients from 18 centers in China with an average age of 71 years old.

The results of this clinical study showed:

(1) The device operation success rate was about 95%; and

(2) The average device operation time was 67.53±43.89 minutes.

The efficacy results showed:

(1) In terms of improvement in mitral regurgitation grade, one-year follow-up results demonstrated that 96.3% of patients had no above moderate regurgitation;

(2) In terms of New York Heart Association cardiac function improvement, one-year follow-up results demonstrated that 93.5% of patients achieved a postoperative cardiac function class I/II; and

(3) In terms of quality of life, one-year follow-up results demonstrated that patients improved their Kansas City Cardiomyopathy Questionnaire scores, on average, by approximately 20 points with an average improvement of approximately 82 meters in the six-minute walking distance.

The safety results showed:

Major Adverse Events (N=114)	**At one year**
All-cause mortality	2 (1.8%)
Unplanned mitral valve intervention/surgery	6 (5.3%)
SLDA	0 (0.0%)
Stroke	2 (1.8%)
Renal failure	1 (0.9%)
Myocardium infarction	1 (0.9%)
Major bleeding	1 (0.9%)
Device related-technique failure	
Device related air embolism	0 (0.0%)
Device releasing/locking failure	1 (0.9%)
Clip related hemolysis	1 (0.9%)
Rehospitalization due to heart failure	3 (2.6%)

JensClip is an innovative medical device designed for the treatment of severe mitral regurgitation with easy and reliable device operation. Its one-year follow-up results demonstrated outstanding performance with an all-cause mortality rate of only 1.8%, only a low incidence of device-related complications, 96.3% of patients had no above moderate regurgitation. In addition, sustained improvement was demonstrated in indicators including New York Heart Association cardiac function, Kansas City Cardiomyopathy Questionnaire scores and six-minute walking distance.

One-Year Follow-Up Results of Ken-Valve

– 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. The study enrolled 142 patients from 15 centers in China with an average age of 70 years old.

The results of this clinical study showed:

(1) The device operation success rate was about 97%; and

(2) The average device operation time was 8.70±8.85 minutes.

The efficacy results showed:

(1) In terms of improvement in aortic regurgitation, one-year follow-up results demonstrated that 94.7% of patients had no above moderate paravalvular leakage;

(2) In terms of New York Heart Association cardiac function improvement, one-year follow up results demonstrated that 96.2% of patients achieved a postoperative cardiac function class I/II;

(3) In terms of improvement in quality of life, one-year follow-up results demonstrated that patients improved their EQ-5D scores, on average, by approximately 19 points; and

(4) In terms of effective orifice area (EOA) and mean transvalvular pressure gradient, one-year follow-up results demonstrated favorable valve function, with EOA and mean transvalvular pressure gradient maintaining stable levels.

The safety results showed:

Major Adverse Events (N=142)	**At one year**
All-cause mortality	8 (5.63%)
Permanent pacemaker implantation rate	20 (14.08%)
III degree AV block	12 (8.45%)
Other types of arrhythmias	8 (5.63%)
Severe bleeding	6 (4.23%)
Stroke	3 (2.11%)
Valve migration	3 (2.11%)
Conversion to surgery	2 (1.41%)
Acute renal dysfunction	1 (0.70%)
Needed for cardiopulmonary mechanical assistance	1 (0.70%)
Coronary artery obstruction	0
Thrombosis	0
Cardiac tamponade	0

The Ken-Valve is an innovative medical device designed for the treatment of patients with severe aortic regurgitation or mixed aortic stenosis predominantly characterized by regurgitation at high surgical risk with easy and reliable device operation. It is suitable for a wide range of anatomical structures. Its one-year follow-up results demonstrated outstanding performance with significant improvement in quality of life, stable EOA and transvalvular pressure gradient, and a low rate of composite adverse events. The Ken-Valve offers six annulus sizes – 23mm, 25mm, 27mm, 29mm, 31mm and 33mm. Its unique innovative design and applicability to complex anatomical challenges, such as large annulus and horizontal heart, can address the treatment needs of patients with large annulus for whom existing treatment options are relatively limited.

The multiple research achievements and clinical application advantages of the Company's comprehensive product portfolio spanning the tricuspid valve, mitral valve and aortic valve received high attention and widespread acclaim from global experts and scholars at the TCT 2025 conference. The Company will rely on a large number of successful clinical application experience, excellent clinical performance, unique and advanced product design, and diversified product portfolio in important countries and regions around the world, including Asia-Pacific, North America, Europe, South America, Australasia, and the Middle East and continue to promote the application and commercialization of its products portfolio around the world.

Save as indicated in this announcement, all the other information and content contained in the October 28 Announcement remain unchanged.

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 JensClip 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, October 29, 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.