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杭州启明醫療器械股份有限公司

Venus Medtech (Hangzhou) Inc.

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

(Stock Code: 2500)

VOLUNTARY ANNOUNCEMENT BUSINESS UPDATE

This announcement is issued by Venus Medtech (Hangzhou) Inc. (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to inform the shareholders and potential investors of the latest information regarding the Group’s latest business development and the research and development progress of new products.

The board of directors of the Company (the “**Board**”) is pleased to announce the interim clinical results of the target study (the “**Target Study**”) of Cardiovalve, the Company’s innovative transcatheter valve replacement system. The Target Study is a prospective, single-arm, multi-center study to evaluate the safety and performance of the Cardiovalve transcatheter valve replacement system. The interim clinical data from Target Study comprises 125 patients with the average age of 77 from 25 active clinical sites in Germany, Spain, Italy, Canada and the UK.

According to the clinical results of the Target Study, (1) the average device operation time was 58±29 minutes, with the shortest device operation time being only 16 minutes; and (2) the overall intraprocedural success rate, per Tricuspid Valve Academic Research Consortium (TVARC) definitions, is 88%. The Device Implanted (DI) subset shows 95% success.

The efficacy results were as follows:

- (1) In terms of improvement in the tricuspid regurgitation grade, 6-month outcomes demonstrated that 100% of patients had no above moderate regurgitation, which was sustained for 12-month outcomes;
- (2) In terms of New York Heart Association cardiac function improvement, 6-month outcomes demonstrated that 88% of patients achieved postoperative cardiac function class I/II, with 90% for 12-month outcomes. There were no New York Heart Association class IV patients in the 6-month follow-up, which was sustained for 12-month follow-up;

- (3) In terms of quality of life, 6-month outcomes demonstrated that patients improved their Kansas City Cardiomyopathy Questionnaire scores, on average, by 20 points, which was sustained for 12-month follow-up. For 6-month follow-up and 12-month follow up, the six-minute walk test showed an average improvement of 44 meters and 32 meters, respectively.

The safety results showed the following:

Clinical Event Committee (CEC) – adjudicated Major Adverse Events (MAE) up to 30 days

Event Term	Intent to Treat (ITT) N=125	Intent to Treat (ITT) – CVU0011 N=57	Intent to Treat (ITT) – CVU0013 N=68
All-Cause mortality	8 (6.4%)	5 (8.8%)	3 (4.4%)
Heart Failure re-hospitalization	2 (1.6%)	1 (1.8%)	1 (1.5%)
Reintervention due to progressive or recurrent TR or device related complications	4 (3.2%)	1 (1.8%)	3 (4.4%)
Major access site and vascular injury requiring surgical intervention	7 (5.6%)	5 (8.8%)	2 (2.9%)
Type IIIb-V Bleeding Academic Research Consortium (BARC) bleeding	16 (12.8%)	12 (21.1%)	4 (5.9%)
Cardiac tamponade	2 (1.6%)	1 (1.8%)	1 (1.5%)
Disabling stroke	1 (0.8%)	0	1 (1.5%)
Acute kidney injury with the need for renal replacement therapy	1 (0.8%)	1 (1.8%)	0
Myocardial infarction	0	0	0
Device related pulmonary embolism	0	0	0

Table above outlines the key differences between the previous Cardiovalve TR Delivery System Model-No.: CVU0011-and the enhanced Cardiovalve-TR Delivery System: Model-No.-CVU0013. For-CE certification, only: Model-No.-CVU0013 is applicable.

In the ITT subset, 26 subjects that are 20.8% of the cohort experienced an MAE by day 30. There were 14 subjects that had two or more reported MAEs, with a total of 41 MAE's.

The 12-month clinical follow-up results of the Target Study demonstrated good safety and performance of Cardiovalve, with continued improvement in the quality of patient's life and a stable, low rate of safety events compared at the 30-day follow-up results. In the Target Study, 65.8% of enrolled patients received large-sized prostheses (55mm). Longer-term follow-up data and global clinical research findings for Cardiovalve continue to be accumulated.

The interim clinical data of Cardiovalve Tricuspid Valve Replacement System, presented at PCR London Valves 2025, demonstrated strong efficacy in treating severe tricuspid regurgitation and received positive recognition from global clinical experts.

The Company remains committed to advancing global clinical development and regulatory registration of its innovative pipeline, including the Cardiovalve System. With a focus on accelerating approvals and market access, Venus Medtech aims to deliver commercially competitive solutions that benefit wider patient populations and support the execution of its global strategy.

Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “Listing Rules”): The Company cannot guarantee that Cardiovalve will ultimately be successfully marketed.

The Company will provide shareholders and investors with further update if and when necessary in accordance with the Listing Rules.

By Order of the Board
Venus Medtech (Hangzhou) Inc.
Mr. Lim Hou-Sen (Lin Haosheng)
Executive Director

Hangzhou, November 19, 2025

As at the date of this announcement, the executive Directors are Mr. Lim Hou-Sen (Lin Haosheng), Mr. Liqiao Ma and Ms. Meirong Liu; the non-executive Directors are Mr. Ao Zhang and Mr. Wei Wang; and the independent non-executive Directors are Mr. Ting Yuk Anthony Wu, Mr. Chi Wai Suen and Mr. John Junhua Gu.