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杭州啓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
COMPLETION OF FULL PATIENT ENROLLMENT FOR CONFIRMATORY CLINICAL STUDY OF CARDIOVALVE TTVR

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 that Cardiovalve, the Company's innovative transcatheter valve replacement system, has recently successfully completed the enrollment of all 150 patients for its Transcatheter Tricuspid Valve Replacement ("**TTVR**") confirmatory clinical study in Europe. This is another significant R&D advancement for Cardiovalve in the treatment of tricuspid regurgitation, marking a crucial step towards CE Mark under the EU Medical Device Regulation approval.

The TARGET confirmatory clinical study is a prospective, multi-center, and single arm study for tricuspid regurgitation. The study was conducted across more than 30 cardiovascular centers in Europe (primarily in Germany, Italy, and Spain), the United Kingdom, and Canada, enrolling a total of 150 patients.

The independently developed Cardiovalve System is a transcatheter interventional replacement product for patients suffering from mitral or tricuspid regurgitation. Compared with products of the same kind, its transfemoral approach significantly improves the safety of treatment and its maximum 55mm annuli is suitable for about 95% of the patient population. Meanwhile, its unique short frame design minimizes the risk of ventricular obstruction. Cardiovalve is easy to operate, safe, and highly repeatable, and can be completed in three steps: positioning, anchoring and release.

The Board believes that the completion of the full patient enrollment for European confirmatory clinical trial of Cardiovalve TTVR system is a major milestone in its commercialization process and a significant advancement in innovative therapies for tricuspid regurgitation worldwide. Leveraging the Group's well-established strengths in R&D, manufacturing, and commercialization within the global structural heart disease field, the Company will continue to actively advance the global clinical registration and development process for innovative products, including Cardiovalve. The Company is committed to accelerating the regulatory approval of its competitive product portfolio, thereby benefiting more patients and advancing our global strategic vision.

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

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

Hangzhou, October 24, 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.