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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
VENUSP-VALVE COMPLETED FIRST PATIENT IMPLANTATION IN IDE PIVOTAL CLINICAL TRIAL IN U.S.

This announcement is made by Venus Medtech (Hangzhou) Inc. (the "**Company**") on a voluntary basis. The board of directors of the Company (the "**Board**") is pleased to announce that the Company has initialed the PROTEUS IDE pivotal clinical trial of the self-developed transcatheter pulmonary valve replacement (TPVR) system VenusP-Valve and successfully had the first patient implanted. This marks a significant advancement in the international clinical progress of VenusP-Valve and represents another major international milestone following the approval of CE MDR in April 2022. The commencement of the clinical trial indicates that VenusP-Valve has the potential to be amongst the first Chinese heart valve systems to be approved globally, ranking among the international competition camps in Europe and the United States, which fully demonstrates the R&D and clinical development capability of Chinese innovative devices.

The prospective, multi-center, non-randomized and interventional PROTEUS clinical trial is designed to evaluate the safety and effectiveness of the VenusP-Valve System in patients with native right ventricular outflow tract (RVOT) dysfunction. 60 subjects will be enrolled in this study and the study results will support both the US FDA and the Japanese PMDA for registration.

The clinical trial was granted approval by the U.S. Centers for Medicare and Medicaid Services (CMS) for inclusion in the medical insurance program in December 2023, allowing patients eligible for the CMS medical insurance plans in the VenusP-Valve clinical trial to reimburse the treatment expenses, which is conducive to promoting patients' active participation and accelerating the progress of clinical trial.

Following its first clinical implantation in 2013, VenusP-Valve has been applied in clinical practice for 11 years. Up to now, the device has been included in national health insurance programs in Germany, France and etc., and has been registered and marketed in more than 50 countries, including China, Germany, France, the United Kingdom, Italy, Spain, Canada, and Australia, with its implantation seeing continuous growth in new hospitals and centers.

As the first self-expanding TPVR product approved in China and Europe, VenusP-Valve carries remarkable clinical value. Uniquely designed with both flared ends, the product ensures the blood flow of branchial artery with bare stents at the outflow end. It provides a stable multi-point anchoring system and enables easy delivery, with no need for pre-stenting before the procedure. Available in a variety of specifications with extensive applicability, VenusP-Valve is able to meet the needs of 85% of patients in the case of large RVOT.

According to three-year follow-up results of the clinical trial in Europe, the product demonstrated 100% procedural success rate and 0% all-cause mortality and reoperation rate among 81 patients who underwent TPVR procedures. Right ventricular function improved significantly. Only one patient had server pulmonary regurgitation.

The initiation of the pivotal clinical trial for VenusP-Valve marks a significant step for the Company in entering key global markets. The Board is looking forward to the rapid completion of patient enrollment and follow-up results to support its approval in U.S. and providing premium and innovative treatment options for patients and physicians around the world.

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 VenusP-Valve will ultimately be successfully marketed.

CONTINUED SUSPENSION OF TRADING

Trading in the shares of the Company on the Stock Exchange of Hong Kong Limited has been suspended with effect from 9:00 a.m. on November 23, 2023 and will remain suspended pending the fulfillment of the resumption guidance as specified by the Stock Exchange of Hong Kong Limited.

Shareholders and potential investors of the Company are advised to exercise caution when dealing in the securities of the Company.

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

Hangzhou, June 13, 2024

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 and Mr. Chi Wai Suen.