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 RECEIVES NMPA APPROVAL

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 on July 11, 2022, VenusP-Valve, the Company's in-house developed innovative transcatheter pulmonic valve replacement (TPVR) system, received the approval of National Medical Products Administration (the "**NMPA**") of the People's Republic of China (the "**PRC**" or "**China**") to be marked in China, marking a new milestone after its CE MDR approval.

As the first TPVR product approved for marketing in China, VenusP-Valve is designed to treat patients with moderate to severe pulmonary regurgitation (≥3+) with native right ventricular outflow tract (RVOT), providing an alternative treatment option for patients. Uniquely designed with both flared ends, the product provides stable anchoring and easy delivery, with no need for pre-stenting before the procedure. The product is available in a variety of specifications with extensive applicability.

Following its first clinical implantation in 2013 by Academician Ge Junbo, Director of Cardiology at Zhongshan Hospital, Fudan University, VenusP-Valve has been used in clinical use for 9 years in nearly 300 cases for humanitarian reasons, spanning more than 20 countries and regions in Asia, Europe, North America, and South America. In April 2022, VenusP-Valve received CE marking under the Medical Devices Regulation (MDR) and has been applied to a number of commercial cases. The product was approved by the FDA for compassionate use in two cases in the U.S. in May 2022 and the first compassionate case was completed successfully in June 2022. In addition, the Investigator Meeting for VenusP-Valve US Clinical Study was held, and the Japan-US Harmonization By Doing Program was agreed upon by the FDA and PMDA with a plan to conduct clinical trials in the U.S. and Japan simultaneously, which will accelerate its registration and marketing in both countries.

For the registration application, the NMPA has accepted VenusP-Valve overseas clinical trials data as clinical evaluation data, that is, the CE clinical trial data was applied. According to the three-year follow-up result of the clinical study in Europe, the product demonstrated 100% procedural success, with no reoperation or death observed in three years. In addition, no moderate or severe pulmonary regurgitation was observed. Meanwhile, the 5-year follow-up of the clinical study in China was completed, and the data reported a 3.64% postoperative 5-year all-cause mortality rate. Pulmonary regurgitation was significantly relieved, which indicated its excellent performance, robust safety and reliability, and drastic and steady improvements in patients' cardiac function.

The Board believes that the launch of VenusP-Valve in China cements the Company's leadership in the structural heart disease treatment in China. The Company will continue to accelerate the clinical trials and global launch of VenusP-Valve, and looks forward to the benefits it brings to more patients worldwide.

Cautionary Statement required by Rule 18A.05 of the Listing Rules: The Company cannot guarantee that VenusP-Valve will ultimately be successfully marketed.

By order of the Board
Venus Medtech (Hangzhou) Inc.
Min Frank Zeng
Chairman

Hangzhou, July 12, 2022

As at the date of this announcement, the executive Directors are Mr. Min Frank Zeng, Mr. Zhenjun Zi and Mr. Lim Hou-Sen (Lin Haosheng); the non-executive Director is Ms. Nisa Bernice Wing-Yu Leung; and the independent non-executive Directors are Mr. Ting Yuk Anthony Wu, Mr. Wan Yee Joseph Lau and Mr. Chi Wai Suen.