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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 OBTAINED FDA IDE APPROVAL

The board (the "**Board**") of directors (the "**Director(s)**") of Venus Medtech (Hangzhou) Inc. (the "**Company**" or "**Venus Medtech**") is pleased to announce that the Company's self-developed transcatheter pulmonary valve replacement (TPVR) system VenusP-Valve received the approval of IDE (Investigational Device Exemption) application from the US Food and Drug Administration(FDA). VenusP-Valve is the first China's domestically developed heart valvular system with full approval to conduct clinical trial by the US FDA.

An IDE is the exemption of investigational devices for marketing purposes from different levels of regulatory controls to conduct clinical trials of medical devices. The approved IDE means VenusP-Valve is allowed to initiate a pivotal clinical study to support the pre-market approval (PMA). Through the Japan-US Harmonization By Doing program, jointly established by the U.S. FDA and the PMDA of Japan, the clinical study will be conducted simultaneously at 10 sites in the United States and 5 sites in Japan and 60 patients are expected to be enrolled.

VenusP-Valve received CE marking under the Medical Devices Regulations (CE MDR) on April 8, 2022, which is the first Class III Implantable cardiovascular device approved under CE MDR. Up to now, VenusP-Valve has covered more than 30 mainstream countries such as China, the United Kingdom, Italy, Spain, Denmark, Greece, France, Germany, Poland, Switzerland, and continues to achieve implantations in newly covered medical institutions.

As the first self-expanding TPVR product approved for marketing in both China and Europe, VenusP-Valve sets itself apart with 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 easy delivery, with no need for pre-stenting before the procedure. Available in a variety of specifications with extensive applicability, VenusP-Valve can meet the needs of 85% of patients in the case of large right ventricular outflow tract (RVOT).

According to the three-year follow-up result of the clinical study in Europe, the product demonstrated 100% procedural success rate among 64 patients who underwent TPVR procedure (some patients were not included due to the covid), 0% all-cause mortality and reoperation rate. In addition, no moderate or severe pulmonary regurgitation was observed and 96.87 percent of patients had mild or less perivalvular leakage (PVL) and tricuspid regurgitation

The approval of VenusP-Valve's IDE application signifies a major milestone in internationalization strategy for the Company, and the Board is looking forward to VenusP-Valve's completion of patient enrollment and clinical follow-up results, supporting its approval in the US market and offering global patients and physicians a premier innovative treatment option.

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

Hangzhou, August 6, 2023

As at the date of this announcement, the executive Directors are Mr. Min Frank Zeng, Mr. Zhenjun Zi and Ms. Meirong Liu; the non-executive Director is Mr. Ao Zhang; and the independent non-executive Directors are Mr. Ting Yuk Anthony Wu, Mr. Wan Yee Joseph Lau and Mr. Chi Wai Suen.