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 TRIAL OF LIWEN RF IN CHINA

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 March 3, 2023, the Liwen RF ablation system developed by the Company for treatment of obstructive hypertrophic cardiomyopathy (HOCM) has successfully enrolled one patient at West China Hospital, Sichuan University, thus completing the enrollment of patients for confirmatory clinical trial in China.

Hypertrophic cardiomyopathy (HCM) is a common hereditary cardiovascular disease worldwide and the leading cause of sudden cardiac death (SCD) in adolescents and athletes, with epidemiological studies in the United States, Japan and Europe indicating a prevalence rate of 0.17%-0.23% and an estimated 20 million cases worldwide. The prevalence in China is approximately 0.18%, on which basis it is estimated that there are over 2 million cases in China. Approximately 40%-60% patients are caused by gene mutations in the myocardial sarcomere, which means that it is still difficult to significantly reduce morbidity in the future through treatment of the existing patient population. In addition, the cases of HCM are significantly underestimated with a clinical diagnosis rate of only 10% due to the lack of a standardised genetic screening system and limited application of imaging technology, which is an important reason for the high number of SCD in China.

The Liwen RF ablation system is independently developed by Hangzhou Nuocheng Medical Technology Co., Ltd. (杭州諾誠醫療科技有限公司), a wholly-owned subsidiary of the Company, and completed an exploratory clinical trial enrolled 144 patients and entered the multi-center confirmatory clinical trial in China in January 2021. The clinical trial was led by Professor Liwen Liu of The First Affiliated Hospital of Air Force Medical University as the principal investigator (PI), with academicians Junbo Ge of Zhongshan Hospital, Fudan University and Yun Zhang of Qilu Hospital of Shandong University as co-PIs, and completed enrollment of 128 patients in 20 centers, including The First Affiliated Hospital of Air Force Medical University, Zhongshan Hospital, Fudan University, Qilu Hospital of Shandong University, the Second Affiliated Hospital, Zhejiang University School of Medicine, West China Hospital Sichuan University, Guangdong Provincial People's Hospital, Xiamen Cardiovascular Hospital Xiamen University, University of Health and Rehabilitation Sciences Qingdao Hospital, Qingdao Municipal Hospital, the 7th People's Hospital of Zhengzhou, The First Affiliated Hospital of Dalian Medical University and Shanxi Cardiovascular Hospital.

Exploratory clinical results showed that compared with the traditional gold standard surgical procedure, the Liwen RF ablation system had an 88% success rate, no death case after operation one year, and significant improvements in patients' clinical performance, cardiac function and quality of life, and was significantly better than septal myectomy surgery and alcohol septal ablation, providing strong evidence of its safety and efficacy and superior performance. In addition, a recent study was published by Professor Liwen Liu's team in the JAMA Cardiology in March 2022. The medium to long-term follow-up of 200 HCM patients treated with the Liwen procedure showed that the Liwen procedure is effective in reducing complications and mortality, and required no permanent pacemaker implantation, reaffirming the long-term safety and efficacy of the product.

With its technical advantages of minimal trauma, precise positioning, unrestricted by target blood vessels, significant reduction in septal ventricular thickness and reduced complications such as conduction system damage, the Liwen RF system offers a safe, effective, precise, minimally invasive and innovative treatment option for HOCM patients. In August 2022, the product was approved for special review through the special examination and approval of the National Medical Products Administration for innovative medical devices.

There are no well-established therapies for HCM globally, and current mainstream treatment improves patients' clinical symptoms and cardiac function to control complications and prevent disease progression. Mavacamten has received the most attention in the HCM therapeutic area in recent years. In October 2020, Bristol-Myers Squibb (BMS) announced that it would acquire MyoKardia for US$13.1 billion in cash at a premium of 60%, in order to obtain its new drug candidate, mavacamten, an allosteric inhibitor of myocardial myosin, which can be used for the treatment of HOCM. The clinical results showed that although mavacamten can relieve obstruction, reached the primary and secondary clinical endpoints, it fails to reduce the ventricular septal thickness and has limited effect in patients with severe HOCM. Septal myectomy surgery requires an open-chest procedure, which is traumatic, risky, prone to damage the conduction bundle, thus causing conduction block and eventually heart failure, and is highly demanding on the operator; alcohol septal ablation does not completely relieve left ventricular outflow tract obstruction in patients with a mismatch between the first septal branch and the site of obstruction; and implantable cardioverter-defibrillator (ICD) is currently the only effective treatment to prevent SCD in patients with HCM, but the ICD affects the quality of life of patients due to electric shock, has a high rate of complications and fails to reduce septal thickness. The advent of the Liwen procedure offers the possibility of safe and effective treatment of HOCM.

The Board believes that the completion of the full patient enrollment for confirmatory clinical trial of Liwen RF in China is a major milestone in its commercialisation process and a significant advancement in innovative therapies for hypertrophic cardiomyopathy worldwide. With the Company's well-established strengths in research, development, manufacturing and commercialisation in the field of structural heart disease, we hope that the Liwen RF ablation system will soon be available for the benefit of patients.

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

Hangzhou, March 3, 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.