LEPU SCIENTECH MEDICAL TECHNOLOGY (SHANGHAI) CO., LTD.*
樂普心泰醫療科技(上海)股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 2291)

VOLUNTARY ANNOUNCEMENT
ScienCrown® TRANSCATHETER AORTIC VALVE REPLACEMENT SYSTEM PRODUCT OBTAINS MEDICAL DEVICE REGISTRATION CERTIFICATE

The board of directors (the "**Board**") of LEPU ScienTech Medical Technology (Shanghai) Co., Ltd.* (the "**Company**") is pleased to announce that the medical device registration certificate for the ScienCrown® Transcatheter Aortic Valve Replacement System ("**ScienCrown® TAVR System**") has been granted by the National Medical Products Administration of the People's Republic of China (Lepu Medical Technology (Beijing) Co., Ltd.* (樂普(北京)醫療器械股份有限公司) as the medical device registrant).

The structural design of the ScienCrown® TAVR System is based on clinical practice needs, effectively addressing existing challenges in transcatheter aortic valve replacement surgery, such as inadequate valve expansion, imprecise positioning, displacement risks, and coronary artery obstruction. It has achieved multiple innovative breakthroughs and has been granted several patents. The product features the following characteristics and advantages: (1) the use of anti-calcified bovine pericardial valve leaflets offers greater durability; and the short valve frame does not block the coronary artery opening, ensuring that the coronary re-intervention surgery can be performed safely and effectively; (2) the self-expanding straight tube design combines strong compliance and stable support, providing a larger valve opening area, effectively reducing pressure gradients, and minimizing long-term complications; (3) the full hanging connection paired with a pre-bending delivery system allows smooth arch passage and coaxial release, which enables stable retrieval and repeat positioning, making it convenient and safe to operate; and (4) the dual access methods through both transfemoral artery and transapical artery provide more options for interventional treatment to meet diverse clinical needs.

With the accelerating global aging process, the incidence of cardiovascular diseases (including aortic stenosis) continues to rise, leading to a year-on-year increase in patients with aortic valve disease worldwide and in China. According to relevant industry consultants' statistics, China had approximately 4.4 million patients with aortic valve stenosis in 2020, with projections indicating an increase to 5.2 million by 2030. Based on the "2023 Annual Report on Transcatheter Aortic Valve Replacement," as of November 30, 2023, China had performed 13,572 transcatheter aortic valve replacement surgeries (cumulative total of 37,552 cases), with an estimated annual implantation volume of approximately 20,000 cases for the year of 2024. In recent years, the transcatheter aortic valve replacement surgeries have demonstrated a rapid growth trend overall. The approval of the Company's ScienCrown® TAVR System brings a new therapeutic option for patients suffering from aortic stenosis. Compared with the traditional aortic valve replacement, the technology of transcatheter aortic valve replacement offers significant advantages such as no thoracotomy requirement, elimination of cardiopulmonary bypass, minimal invasiveness, and faster recovery and is gradually becoming the preferred treatment option for aortic valve stenosis in clinical practice. With the broader adoption of this technology and accumulating clinical experience, ScienCrown® TAVR System demonstrates tremendous potential in clinical applications.

Looking ahead, the Company remains committed to advancing innovation and will continue to enhance clinical collaboration, optimize product performance, expand application scenarios, and drive technological advancement in cardiovascular intervention, ultimately benefiting more patients in need.

The sales performance of ScienCrown® TAVR System will be subject to a number of factors including but not limited to clinical promotion, channel expansion, changes in competitive landscape and macro policies, for which there exist uncertainties of this product on the Company's financial performance.

Shareholders of the Company and potential investors should exercise caution when dealing in the securities of the Company.

By order of the Board
LEPU ScienTech Medical Technology (Shanghai) Co., Ltd.*
樂普心泰醫療科技(上海)股份有限公司
Ms. Chen Juan
Chairman of the Board and Executive Director

Shanghai, the People's Republic of China
December 17, 2024

As at the date of this announcement, the Board comprises Ms. Chen Juan as executive Director, Ms. Zhang Yuxin, Mr. Fu Shan and Mr. Zhu Guanfu as non-executive Directors, and Ms. Chan Ka Lai Vanessa, Mr. Zheng Yufeng, and Mr. Zheng Junwei as independent non-executive Directors.

* *The Company is a registered non-Hong Kong company as defined under the Companies Ordinance (Chapter 622 of the Laws of Hong Kong) and it is registered under its Chinese name and under the English name "LEPU ScienTech Medical Technology (Shanghai) Co., Ltd.".*