

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



Peijia Medical Limited

沛嘉醫療有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 9996)

VOLUNTARY ANNOUNCEMENT

FIRST PATIENT IMPLANT IN MULTI-CENTER REGISTRATION CLINICAL TRIAL OF PEIJIA HighLife® TRANSCATHETER MITRAL VALVE REPLACEMENT SYSTEM IN CHINA

This announcement is made by Peijia Medical Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to provide the shareholders of the Company and potential investors with updated information in relation to the latest business and new product development progress of the Group.

The board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce that the Company has enrolled the first patient of the multi-center registration clinical trial for Peijia HighLife® Transcatheter Mitral Valve Replacement (trans-septal mitral valve replacement, “**TSMVR**”) system (the “**System**”), and the first implant has been successfully completed by West China Hospital, Sichuan University. The registration clinical trial of Peijia HighLife® TSMVR system is a single-arm, prospective, multi-center study of assessing the safety and efficacy of the System for treating patients with moderate to severe or severe mitral regurgitation. The study is led by Professor Chen Mao from West China Hospital, Sichuan University and involves twelve top centers across China. Results from this multi-center registration clinical trial would be included in the Company’s future submission of registration application to the National Medical Products Administration (the “**NMPA**”).

The System is based on the technology developed by and transferred from HighLife SAS and is manufactured by the Company in China. The System employs a unique “Valve-in-Ring” concept, which makes it self-centering and self-aligning. The 2-component design respectful for mitral valve anatomy can be adapted to a large majority of patients. The design of the System can mitigate the risk of paravalvular leakage and effectively reduce catheter size.

As of the date of this announcement, Peijia HighLife® TSMVR system was formally accepted by the Special Review and Approval Procedure (the “**Procedure**”) for Innovative Medical Devices of the NMPA, and will enjoy advantages including expedited approval, as well as favorable policy support. The System is the fourth transcatheter valve therapeutic medical device of the Company, which was formally accepted by the Procedure.

Reference is made to the Company’s announcement dated December 28, 2021. On December 22, 2021, Professor Mao Chen and his team from West China Hospital, Sichuan University completed the first patient implant of the research clinical trial for Peijia HighLife® TSMVR system. Currently, the research clinical trial is progressing smoothly.

THE COMPANY MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET PEIJIA HighLife® TSMVR SYSTEM SUCCESSFULLY. SHAREHOLDERS OF THE COMPANY AND POTENTIAL INVESTORS ARE ADVISED TO EXERCISE DUE CARE WHEN DEALING IN THE SHARES OF THE COMPANY.

By order of the Board
Peijia Medical Limited
Dr. Yi Zhang
Chairman and Executive Director

Hong Kong, November 14, 2022

As of the date of this announcement, the Board comprises Dr. Yi Zhang, Mrs. Ping Ye Zhang and Ms. Hong Ye as executive Directors, Dr. Zhiyun Yu, Mr. Jifeng Guan, Mr. Fei Chen, Mr. Jun Yang as non-executive Directors, and Dr. Stephen Newman Oesterle, Mr. Robert Ralph Parks, Mr. Wai Ming Yip and Mr. Huacheng Wei as independent non-executive Directors.