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**LEPU BIOPHARMA CO., LTD.**  
**樂普生物科技股份有限公司**

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

**(Stock Code: 2157)**

**VOLUNTARY ANNOUNCEMENT**

**ORPHAN-DRUG DESIGNATION GRANTED BY THE  
FDA TO MRG004A FOR THE TREATMENT OF  
PANCREATIC CANCER**

**A. INTRODUCTION**

This announcement is made by Lepu Biopharma Co., Ltd. (the “**Company**”) on a voluntary basis to provide information to the shareholders and potential investors of the Company.

The board of directors of the Company (the “**Board**”) is pleased to announce that our drug candidate MRG004A, a novel tissue factor-targeted site-specifically conjugated antibody drug conjugate, for the treatment of pancreatic cancer has been granted the Orphan-drug Designation by the Food and Drug Administration of the United States (the “**FDA**”) recently. Previously, in February 2021, we received an investigational new drug (the “**IND**”) clearance for MRG004A from the FDA for Phase I/II clinical trials in the United States. In August 2021, we also received an IND approval for MRG004A from the National Medical Products Administration of the People’s Republic of China (the “**PRC**” or “**China**”).

**B. ABOUT MRG004A**

MRG004A is a novel tissue factor-targeted site-specifically conjugated antibody drug conjugate. We are currently conducting a Phase I/II clinical study in the United States and China. We have observed anti-tumor activity signal on pancreatic cancer, triple-negative breast cancer and cervical cancer.

**C. IMPACT OF THE DESIGNATION ON THE COMPANY AND RISK WARNING**

The Orphan-drug Designation obtained from the FDA will help MRG004A enjoy certain incentives for the follow-up research and development, registration and commercialization of designated drugs for the treatment of pancreatic cancer in the United States, including but not limited to (1) tax credits for qualified clinical trials; (2) exemption from user fees; and (3) potential seven years of market exclusivity after approval.

**Warning:** There is no assurance that the Company will ultimately develop, launch and/or commercialize the product successfully. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By order of the Board  
**Lepu Biopharma Co., Ltd.**  
**Dr. Pu Zhongjie**  
*Chairman of the Board and Executive Director*

Shanghai, the PRC  
December 14, 2023

*As at the date of this announcement, the Board comprises Dr. Pu Zhongjie (chairman), Dr. Sui Ziyue (chief executive officer) and Dr. Hu Chaohong (co-chief executive officer) as executive directors; Ms. Pu Jue, Mr. Yang Hongbing and Mr. Lin Xianghong as non-executive directors; and Mr. Zhou Demin, Mr. Yang Haifeng and Mr. Fengmao Hua as independent non-executive Directors.*