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.



## 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**

# FAST TRACK 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.

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, has been granted the Fast Track Designation (the "FTD") by the Food and Drug Administration of the United States (the "FDA") for the treatment of pancreatic cancer.

Previously, in December 2023, we received the Orphan-drug Designation (the "**ODD**") for MRG004A from the FDA.

The FTD is established to facilitate and expedite the clinical development and review process of drugs with a view to meeting the unmet medical demands of serious or life-threatening diseases. According to the relevant regulations, the obtainment of FTD status for drug candidates would provide the opportunity to accelerate the review process in various forms.

### 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 in pancreatic cancer, triple-negative breast cancer and cervical cancer.

### C. IMPACT ON THE COMPANY

This obtainment of the FTD marks another important milestone for the Company, which comes shortly after MRG004A was granted the ODD from the FDA.

**Warning:** There is no assurance that the MRG004A will ultimately be successfully developed and marketed by the Company. 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 March 11, 2024

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