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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**

### **BREAKTHROUGH THERAPY DESIGNATION GRANTED BY THE FDA TO MRG003 FOR THE TREATMENT OF R/M NPC**

#### **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 MRG003, an antibody drug conjugate (“**ADC**”) drug candidate targeting epidermal growth factor receptor (“**EGFR**”) and a core product of the Company, has recently been granted the Breakthrough Therapy Designation (“**BTD**”) by the Food and Drug Administration of the United States (the “**FDA**”) for the treatment of recurrent or metastatic nasopharyngeal cancer (“**R/M NPC**”).

Previously, MRG003 has already been granted BTD by the Center for Drug Evaluation (the “**CDE**”) of the National Medical Products Administration of the People’s Republic of China (the “**PRC**”), the Orphan-drug Designation (“**ODD**”) by the FDA and the Fast Track Designation (“**FTD**”) by the FDA for the treatment of R/M NPC. The Company has also already completed patient enrollment of the registrational Phase IIb clinical study for MRG003 on nasopharyngeal cancer (“**NPC**”) and we expect to file new drug application in the PRC soon.

BTD aims to facilitate and expedite development and review of new drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapies. A drug that receives BTD is eligible for the intensive guidance on an efficient drug development and organizational commitment involving senior managers to ensure earlier patient access to new treatment options. The success of MRG003 being designated as breakthrough therapy by the FDA for the treatment of R/M NPC signifies the FDA’s recognition of the clinical data of our drug candidate, and verifies our breakthrough therapy. It will support the overseas commercialization of MRG003, establishing a solid foundation for the Company’s internationalization and making a significant step towards this goal.

## B. ABOUT MRG003

MRG003 is an ADC comprised of an EGFR-targeted monoclonal antibody conjugated with the potent microtubulin inhibiting payload monomethyl auristatin E via a valine-citrulline linker. It binds specifically with high affinity to EGFR on the surface of tumor cells, releases the potent payload upon internalization and lysosomal protease cleavage of the linker and results in tumor cell death.

EGFR is highly expressed in colorectal cancer, lung cancer, head and neck cancer and other malignant solid tumors, and is expressed in 89% advanced NPC. Therefore, EGFR is an important target for cancer treatment.

## C. IMPACT ON THE COMPANY

MRG003 is a globally advanced EGFR-targeted ADC in clinical development stage and has the potential to seize market opportunities. This obtainment of BTD from the FDA marks another important milestone for the Company, after MRG003 has been granted FTD and ODD from the FDA and BTD from the CDE.

**Warning:** There is no assurance that the MRG003 will ultimately be successfully developed and marketed by the Company. Shareholders of the Company and potential investors 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  
August 5, 2024

*As at the date of this announcement, the Board comprises Dr. Pu Zhongjie (chairman) and 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.*