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 CDE TO MRG003 FOR THE TREATMENT OF R/M NPC

A. INTRODUCTION

This announcement is made by Lepu Biopharma Co., Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis.

The board of directors of the Company (the "**Board**") is pleased to announce that, on 29 September 2022, the Center for Drug Evaluation (the "**CDE**") of the National Medical Products Administration (the "**NMPA**") of the People's Republic of China (the "**PRC**") has granted MRG003 breakthrough therapy designation for the treatment of recurrent or metastatic nasopharyngeal cancer ("**R/M NPC**"). MRG003 is an antibody drug conjugate ("**ADC**") drug candidate targeting epidermal growth factor receptor ("**EGFR**") and a core product of the Company.

Previously, MRG003 has been granted the Orphan-drug Designation by the Food and Drug Administration of the United States (the "**FDA**") for the treatment of R/M NPC.

Breakthrough therapy designation is for innovative or modified new drugs that treat a condition that is seriously life-threatening or has serious quality-of-life impairment, and such condition has no effective therapies or compared with current available therapies, sufficient evidence demonstrates an obvious advantage in clinic treatment of the new drugs. According to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) and the announcement of the NMPA's publication of three documents including the Working Procedures for Review of Breakthrough Therapeutics (Trial) (No. 82 of 2020) (《國家藥監局關於發佈＜突破性治療藥物審評工作程序(試行)＞等三個文件的公告》(2020年第82號)), drugs granted the breakthrough therapy designation are prioritized by the CDE in communications and guidance to promote the drug development progress. Breakthrough therapy designation brings forward the expedited point of marketing of drugs to the clinical trial stage and can help to submit new drug application in an expedited way as well as shorten its evaluation time.

B. ABOUT MRG003

MRG003 is an ADC comprised of an EGFR-targeted monoclonal antibody ("**mAb**") conjugated with the potent microtublin inhibiting payload monomethyl auristatin E ("**MMAE**") 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.

In China, the Company is conducting exploring research of MRG003 in several indications and amongst others, patient enrollment was completed in March 2022 for exploratory Phase II clinical study of MRG003 in advanced NPC. It has entered the follow-up period and clinical data is outstanding.

C. IMPACT ON THE COMPANY

MRG003 is the most advanced EGFR-targeted ADC in clinical-stage development in China and has the potential to seize market opportunities. The breakthrough therapy designation, which helps to expedite the development and review of the drug by the CDE, represent an encouraging signal to the promotion of MRG003 as well as the strategy of developing market-differentiating pipeline of the Company.

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, September 29, 2022

As at the date of this announcement, the board of directors of the Company comprises Dr. Pu Zhongjie (Chairman), Dr. Sui Ziye (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.