

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 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 been granted the Fast Track Designation (the “**FTD**”) by the Food and Drug Administration of the United States (the “**FDA**”) for the treatment of recurrent or metastatic nasopharyngeal cancer (“**R/M NPC**”) recently.

Previously, MRG003 has already been granted breakthrough therapy designation (the “**BTD**”) by the Center for Drug Evaluation (the “**CDE**”) of the National Medical Products Administration of the People’s Republic of China (the “**PRC**”) and the Orphan-drug Designation (the “**ODD**”) by the FDA for the treatment of R/M NPC.

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 diseases. According to the regulations, the obtainment of FTD status for drug candidates would provide the opportunity to accelerate the review process in various forms.

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 an advanced EGFR-targeted ADC in clinical-stage development in China and has the potential to seize market opportunities. This obtainment of the FTD marks another important milestone for the Company, which comes shortly after MRG003 was granted the ODD from the FDA and BTB 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
December 4, 2023

As at the date of this announcement, the Board 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.