

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

**COMPLETION OF PATIENT ENROLLMENT OF
PIVOTAL PHASE IIb CLINICAL TRIAL FOR
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 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 MRG003, an antibody drug conjugate (“**ADC**”) drug candidate targeting epidermal growth factor receptor (“**EGFR**”) and a core product of the Company, has successfully completed the enrollment of all patients in the Pivotal Phase IIb clinical trial for the treatment of recurrent or metastatic nasopharyngeal cancer (“**R/M NPC**”) recently.

This trial is a randomized, open-label, multicenter Pivotal Phase IIb clinical study, which started patient enrollment in April 2023, in respect of which 173 participants have successfully completed enrollment as of the date of this announcement.

Previously, MRG003 has been granted the breakthrough therapy designation by the Center for Drug Evaluation of the National Medical Products Administration of the People's Republic of China (the “**PRC**”), the Orphan-drug Designation by the Food and Drug Administration of the United States (the “**FDA**”) for the treatment of R/M NPC and the Fast Track Designation by the FDA.

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

The Pivotal Phase IIb clinical trial of MRG003 in China aims to research and evaluate the safety, preliminary efficacy and optimal dosing strategy of MRG003 for the treatment of R/M NPC, and to accumulate more data to comprehensively evaluate the risks and benefits of later clinical trials in order to accelerate the global development process of the product.

Warning: There is no assurance that 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 29, 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.