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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

UPDATE ON NEW DRUG APPLICATION OF MRG003

This announcement is made by Lepu Biopharma Co., Ltd. (the “**Company**”) on a voluntary basis. Reference is made to the announcement of the Company on September 27, 2024 (the “**Announcement**”) with respect to the New Drug Application (“**NDA**”) of our drug candidate MRG003, an antibody drug conjugate (“**ADC**”) drug candidate targeting epidermal growth factor receptor (“**EGFR**”), for the treatment of recurrent or metastatic nasopharyngeal cancer (“**R/M NPC**”).

UPDATE ON NDA OF MRG003

As disclosed in the Announcement, we have received the Acceptance Notice (《受理通知書》) issued by China National Medical Products Administration (“**NMPA**”) in relation to the acceptance of the NDA of MRG003 in September 2024, and has been granted priority review by the Centre for Drug Evaluation (“**CDE**”) of the NMPA (the “**Priority Review**”).

The authority is currently proceeding with the clinical and pharmaceutical evaluation of MRG003 in an orderly manner. Based on the latest communication between the Company and the authority, in order to submit relevant supplementary information, the Company has voluntarily withdrawn the previous NDA of MRG003, and has already supplemented relevant application materials and prepared the eCTD documents. The Company will resubmit an NDA for MRG003 on March 4, 2025 and will use its best endeavors to work with the authority in its subsequent review procedures to obtain the NDA approval.

The Company expresses regret for any possible delay to the NDA approval of MRG003 brought about by the re-submission of NDA owing to the need for submission of supplementary materials.

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.

Warning: There is no assurance that the MRG003 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 4, 2025

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