

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

**THE PIVOTAL CLINICAL TRIAL RESULTS FOR MRG003 PRESENTED
AS LBA AT 2025 ASCO ANNUAL MEETING**

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, the results of the pivotal clinical trial study for the treatment of recurrent or metastatic nasopharyngeal cancer (“**R/M NPC**”) for our drug candidate MRG003, an innovative antibody drug conjugate (“**ADC**”) drug candidate independently developed by us targeting epidermal growth factor receptor, were presented as “late breaking abstract (LBA)” for oral presentation at the 2025 American Society of Clinical Oncology (the “**ASCO**”) Annual Meeting.

B. ORAL ABSTRACT SESSION (LBA)

- **Becotatug Vedotin vs. Chemotherapy in pre-heavily treated advanced nasopharyngeal carcinoma: A Randomize-controlled, Multicenter, Open-label Study**

MRG003 is a novel EGFR-targeted antibody-drug conjugate. Previous Phase I/II studies have demonstrated optimistic efficacy in recurrent/metastatic nasopharyngeal carcinoma (“**R/M NPC**”) patients who had failed after platinum chemotherapy and PD-(L)1 inhibitor. We have presented orally the clinical efficacy and safety results of MRG003 compared with chemotherapy from the randomized-controlled study in patients with R/M NPC at the 2025 ASCO Annual Meeting, which are summarized as follows:

173 R/M NPC patients were enrolled, with 86 patients randomly assigned to MRG003, 87 patients randomly assigned to Chemotherapy. The median prior treatment lines (range) were 3 (2-11). By 30 June 2024, the study reached the significantly improved blinded independent central review (“**BICR**”) assessed objective response rate (“**ORR**”) with MRG003 (30.2%) compared to chemotherapy (11.5%) (95%CI: 7.0%, 30.5%, P=0.0025). Also, progression-free survival (“**PFS**”) was significantly improved in the MRG003 arm (HR=0.63, 95%CI: 0.43, 0.91, P=0.0146). Median PFS (95%CI) by BICR were 5.8 months (4.2, 6.2) vs. 2.8 months (2.0, 5.5). As of the interim analysis on 30 December 2024, the median overall survival (“**OS**”) (95%CI) were 17.1 months (11.4, NE) vs. 12.0 months (9.7, 15.4) of two arms (HR=0.73, 95%CI: 0.48, 1.12), mOS is not mature. By supplementary analysis excluding the impact of crossover treatment, the HR of OS was 0.59 (95%CI: 0.37, 0.93). MRG003 has shown a clear trend of survival benefits. The OS will be continually followed up. The incidence of adverse events in the two arms was similar.

As the first ADC clinical study targeting heavily pretreated R/M NPC population, MRG003 demonstrated statistically and clinically meaningful benefits while maintaining a manageable safety profile in patients who failed ≥ 2 lines of systemic chemotherapy and PD-(L)1 inhibitor. This study will lead to a paradigm shift in the treatment of R/M NPC.

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
June 1, 2025

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.