Shanghai Henlius Biotech, Inc.
上海復宏漢霖生物技術股份有限公司
(A joint stock company incorporated in the People's Republic of China with limited liability)
(Stock code: 2696)

VOLUNTARY ANNOUNCEMENT

THE FIRST PATIENT HAS BEEN DOSED IN A PHASE 1 CLINICAL STUDY OF HLX3901 INJECTION (DLL3xDLL3xCD3xCD28 TETRA-SPECIFIC ANTIBODY) FOR THE TREATMENT OF PATIENTS WITH ADVANCED SMALL CELL LUNG CANCER OR NEUROENDOCRINE CARCINOMA IN CHINESE MAINLAND

A. INTRODUCTION

This announcement is made by Shanghai Henlius Biotech, Inc. (the "**Company**") on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business development of the Company.

The board of directors of the Company (the "**Board**") is pleased to announce that, recently, the first patient has been dosed in a phase 1 clinical study of HLX3901 injection (DLL3xDLL3xCD3xCD28 tetra-specific antibody) ("**HLX3901**") for the treatment of patients with advanced small cell lung cancer or neuroendocrine carcinoma in Chinese Mainland (excluding Hong Kong, Macau and Taiwan regions of China).

B. CLINICAL TRIAL DESIGN AND OBJECTIVES

This is an open-label, first-in-human phase 1 clinical study to evaluate the safety, tolerability, pharmacokinetic profiles, and preliminary efficacy of HLX3901 in patients with advanced small cell lung cancer or neuroendocrine carcinoma. The study consists of two stages: phase 1a dose-escalation and backfill stage and phase 1b dose-expansion stage. Phase 1a includes seven dose levels ranging from 0.1 mg to 30 mg, with a 4-week treatment cycle. The 0.1 mg dose level employs an accelerated titration design, while the remaining six dose levels use a "3+3" dose-escalation design; during the dose-escalation period, after safety validation, subjects are allowed to backfill in some dose groups. Phase 1b is planned to include three dose-expansion cohorts at 10 mg, 20 mg, and 30 mg, with dosing strategies consistent with those used in the corresponding phase 1a dose levels. The primary objectives of this study are to evaluate the safety and tolerability of HLX3901 in patients with advanced small cell lung cancer or neuroendocrine carcinoma, to determine its maximum tolerated dose ("**MTD**") and recommended phase 2 dose ("**RP2D**"), and to preliminarily evaluate its antitumor efficacy. The primary endpoints include the incidence of dose-limiting toxicities (DLTs), the MTD and RP2D of HLX3901, and the investigator-assessed objective response rate (ORR).

C. ABOUT HLX3901

HLX3901 is a tetra-specific antibody drug independently developed by the Company, intended for the treatment of advanced/metastatic solid tumours. HLX3901 is capable of simultaneously targeting DLL3 dual epitopes, CD3 and CD28, acting as a T-cell engager to effectively enhance efficacy of tumour treatment, overcome immune suppression, and improve the therapeutic window of T-cell engager. The mechanism of action of HLX3901 involves (1) enhancing the targeted lysis capacity of T cells against DLL3-positive tumour cells by simultaneously activating CD3 (the first signal) and CD28 (the co-stimulatory signal) on the surface of T cells, thereby improving anti-tumour efficacy; and (2) enhancing the activation, proliferation and in vivo survival of T cells by synergistically activating the first signal and the co-stimulatory signal for T cell activation, thereby prolonging the duration of anti-tumour immune response. Pre-clinical studies showed that HLX3901 demonstrated good anti-tumour efficacy and safety, which is expected to bring clinical benefits. In March 2026, the investigational new drug (IND) application for phase 1 clinical trial of HLX3901 for the treatment of patients with advanced/metastatic solid tumours was approved by the National Medical Products Administration (NMPA).

D. MARKET CONDITION

As of the date of this announcement, there is no tetra-specific antibody targeting DLL3 dual epitopes, CD3 and CD28 approved worldwide.

WARNING STATEMENT WITH REFERENCE TO THE REQUIREMENTS UNDER RULE 18A.05 OF THE RULES GOVERNING THE LISTING OF SECURITIES ON THE STOCK EXCHANGE OF HONG KONG LIMITED: The Company cannot guarantee the successful development and commercialisation of HLX3901. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

On behalf of the Board
Shanghai Henlius Biotech, Inc.
Wenjie Zhang
Chairman

Hong Kong, 30 April 2026

As at the date of this announcement, the board of directors of the Company comprises Mr. Wenjie Zhang as the chairman and non-executive director, Dr. Jun Zhu as the executive director, Mr. Qiyu Chen, Mr. Yuqing Chen, Ms. Xiaohui Guan, Dr. Yi Liu and Dr. Xingli Wang as the non-executive directors, and Mr. Tak Young So, Dr. Lik Yuen Chan, Dr. Ruilin Song and Mr. Yihao Zhang as the independent non-executive directors.