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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

FIRST PATIENT IN AUSTRALIA HAS BEEN DOSED IN AN INTERNATIONAL MULTICENTRE PHASE 2 CLINICAL STUDY OF HLX43 FOR INJECTION (AN ANTI-PD-L1 ANTIBODY-DRUG CONJUGATE) FOR THE TREATMENT OF ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC)

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 in Australia has been dosed in an international multicentre phase 2 clinical study of HLX43 for injection (an anti-PD-L1 antibody-drug conjugate) ("**HLX43**") in patients with advanced non-small cell lung cancer (NSCLC). This phase 2 clinical study is also ongoing in mainland China (excluding Hong Kong, Macau and Taiwan regions of China, the same as below) and the United States.

B. CLINICAL TRIAL DESIGN AND OBJECTIVES

This is an open-label, multicentre, international phase 2 clinical study to evaluate HLX43 in patients with advanced non-small cell lung cancer (NSCLC). This study aims to evaluate the efficacy and safety of HLX43 in advanced non-small cell lung cancer (NSCLC) patients. It consists of two parts: Part 1, which focuses on dose exploration to identify the optimal HLX43 dosage for Part 2; and Part 2, which is a single-arm, multicentre phase 2 clinical trial. The primary objective of this study is to evaluate the clinical efficacy of HLX43 in advanced non-small cell lung cancer (NSCLC) patients. The primary endpoint of the study is objective response rate evaluated by the Blinded Independent Central Review (BICR) according to RECIST v1.1.

C. ABOUT HLX43

HLX43 is an antibody-drug conjugate (ADC) targeting PD-L1 developed by the Company through conjugating the novel DNA topoisomerase I inhibitor payload – licensed-in peptide linker, with antibody targeting PD-L1 independently developed by the Company, which is designed for the treatment of advanced/metastatic solid tumours. As of the date of this announcement, the relevant development progress of HLX43 are as follows:

Product/ Combination therapy	**Indications**	**Latest progress**
HLX43	Advanced/Metastatic solid tumours	Phase 1 clinical trial in mainland China (thymic carcinoma (TC) cohort as international multicentre trial) Permitted to commence the phase 1 clinical trial in the United States and Japan
HLX43	Advanced non-small cell lung cancer (NSCLC)	Phase 2 clinical trials in mainland China, the United States and Australia (International multicentre trial) Permitted to commence the phase 2 clinical trial in Japan
HLX43 monotherapy or combination therapy	Advanced/Metastatic solid tumours	Phase 2 clinical trials for metastatic colorectal cancer (mCRC), cervical cancer (CC), esophageal squamous cell carcinoma (ESCC) and other indications in mainland China
HLX43+ HANSIZHUANG	Advanced/Metastatic solid tumours	Phase 1b/2 clinical trial in mainland China

In September 2025, the phase 1 clinical trial updated results of HLX43 were released at the 2025 World Conference on Lung Cancer (WCLC). The data demonstrated that in patients with advanced tumours, especially in those with NSCLC for whom checkpoint inhibitor therapy and chemotherapy have failed, HLX43 continued to show high response rate and good safety characteristics at all dose levels. Investigator-assessed objective response rate (ORR) was 37.0%, and disease control rate (DCR) was 87.0%. Among others, ORR was 30.0% (3/10) in patients with squamous NSCLC with prior treatment with docetaxel as a third or later-line anti-tumour therapy; ORR was 40.0% in patients with squamous NSCLC who received HLX43 at 2.0 mg/kg. HLX43 exhibited even more favorable efficacy in patients with EGFR wildtype non-squamous NSCLC, with a confirmed ORR of 46.7%. Of these patients, those who received HLX43 at 2.5 mg/kg had a confirmed ORR of 60.0%. For patients with brain metastasis, the confirmed ORR was 36.4% and DCR was 100.0%. Additionally, ORR was 34.4% in programmed death ligand 1 (PD-L1) positive (tumour proportion score (TPS) ≥ 1%) and 38.1% in PD-L1 negative (TPS < 1%) patients.

D. MARKET CONDITION

HLX43 is an antibody-drug conjugate (ADC) targeting PD-L1. As at the date of this announcement, no antibody-drug conjugate targeting PD-L1 has been approved for marketing globally.

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 commercialization of HLX43. 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, 18 September 2025

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.