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 THE UNITED STATES HAS BEEN DOSED IN AN INTERNATIONAL MULTI-CENTER 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 the United States has been dosed in an international multi-center 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 Company proposes to commence clinical trials in Australia, Japan and other countries when the conditions are met.

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 tumors	Phase 1 clinical trial in mainland China (thymic carcinoma (TC) cohort as international multicentre trial) Application for the phase 1 clinical trial was approved in the United States
HLX43	Advanced non-small cell lung cancer (NSCLC)	Phase 2 clinical trial in mainland China and the United States (International multicentre trial) Applications for the phase 2 clinical trials were approved in the United States, Japan, and Australia
HLX43 monotherapy or combination therapy	Advanced/Metastatic solid tumors	Application for the phase 1b/2 clinical trial was approved in mainland China Phase 2 clinical trials for cervical cancer (CC), esophageal squamous cell carcinoma (ESCC) and other indications in mainland China
HLX43+ HANSIZHUANG	Advanced/Metastatic solid tumors	Phase 1b/2 clinical trial in mainland China

The phase 1 clinical trial results of HLX43 were first released at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting. The data demonstrated that HLX43 has good safety profiles across all dose levels and exhibited encouraging anti-tumour activity in patients with advanced/metastatic solid tumours, particularly in non-small cell lung cancer (NSCLC) and thymic squamous cell carcinoma (TSCC).

2025 World Conference on Lung Cancer (WCLC) released the selected research abstracts for this year's conference. Among the highlights is the updated abstract for the first-in-human Phase 1 clinical trial of HLX43. According to the updated abstract, HLX43 has demonstrated promising anti tumour activity along with a manageable safety profile in patients with advanced NSCLC who were refractory to standard therapies, including those who had progressed after treatment with PD-(L)1 inhibitors. Its high efficacy with low toxicity traits support its potential in the first-line settings. HLX43 exhibits superior efficacy in specific subgroups, with an objective response rate (ORR) of 47.4% in EGFR wild-type non-squamous NSCLC, while maintaining a favorable safety profile.

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, 22 August 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. Yifang Wu, Ms. Xiaohui Guan, Mr. Deyong Wen and Dr. Xingli Wang as the non-executive directors, and Mr. Tak Young So, Dr. Lik Yuen Chan, Dr. Guoping Zhao and Dr. Ruilin Song as the independent non-executive directors.