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 AN INTERNATIONAL MULTICENTRE PHASE 2/3 CLINICAL STUDY OF HLX43 FOR INJECTION (AN ANTI-PD-L1 ANTIBODY-DRUG CONJUGATE) AS MONOTHERAPY OR IN COMBINATION WITH PIMURUTAMAB HLX07 (RECOMBINANT ANTI-EGFR HUMANIZED MONOCLONAL ANTIBODY INJECTION) VERSUS DOCETAXEL FOR THE TREATMENT OF ADVANCED/ METASTATIC SQUAMOUS NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE PRIOR TREATMENT HAS FAILED 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 an international multicentre phase 2/3 clinical study of HLX43 for injection (an anti-PD-L1 antibody-drug conjugate) ("**HLX43**") as monotherapy or in combination with pimurutamab HLX07 (recombinant anti-EGFR humanized monoclonal antibody injection) ("**HLX07**") versus docetaxel for the treatment of advanced/metastatic squamous non-small cell lung cancer (NSCLC) whose prior treatment has failed in Chinese Mainland (excluding Hong Kong, Macao and Taiwan regions of China, same as below).

B. CLINICAL TRIAL DESIGN AND OBJECTIVES

This study is a randomized, open-label, international multicentre phase 2/3 clinical trial designed to evaluate the efficacy and safety of HLX43 as monotherapy or in combination with HLX07, compared with docetaxel, for the treatment of advanced or metastatic squamous non-small cell lung cancer (NSCLC) whose prior treatment has failed. The study consists of two stages. Stage I is an open-label, randomized, multicentre phase 2 study in which eligible subjects will be randomized in a 1:1:1:1 ratio to one of the following treatment groups: Group A (HLX43 monotherapy), Group B (HLX43 in combination with HLX07 (1,000 mg)), Group C (HLX43 in combination with HLX07 (600 mg)), or Group D (docetaxel). Stage II is an open-label, randomized, multicentre phase 3 study. Based on the results of Stage I, either HLX43 monotherapy or HLX43 in combination with HLX07 will be selected as the investigational treatment for Stage II. Eligible subjects will then be randomized in a 1:1 ratio to the investigational group (HLX43 monotherapy or HLX43 in combination with HLX07) or the control group (docetaxel). The primary objective of this study is to evaluate the clinical efficacy of HLX43 monotherapy or HLX43 in combination with HLX07, compared with docetaxel, in patients with advanced squamous NSCLC whose disease has progressed after first-line treatment. Overall survival (OS) and progression-free survival (PFS) are the dual primary endpoints. Secondary objectives include evaluation of the safety of HLX43 monotherapy or HLX43 in combination with HLX07 compared with docetaxel, the pharmacokinetic (PK) characteristics and immunogenicity of HLX43 and HLX07, and the exploration of potential predictive or resistance biomarkers.

C. ABOUT HLX43 AND HLX07

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 was as follows:

Product/Combination therapy	**Indications**	**Latest progress**
HLX43	Advanced/Metastatic solid tumours	Phase 1 clinical trial in Chinese Mainland Thymic carcinoma (TC) cohort is an international multi-center trial, currently in phase 1 clinical trial in Japan and the United States
HLX43	Advanced non-small cell lung cancer (NSCLC)	Phase 2 clinical trial in Chinese Mainland, the United States, Australia, Japan and EU country (International multicentre trial)

Product/Combination therapy	Indications	Latest progress
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 Chinese Mainland
HLX43+ HANSIZHUANG	Advanced/Metastatic solid tumours	Phase 1b/2 clinical trial in Chinese Mainland
HLX43+HLX07	Advanced/Metastatic solid tumours	HLX43 in combination with HLX07 or HANSIZHUANG in phase 1b/2 clinical trial for metastatic colorectal cancer (mCRC) in Chinese Mainland HLX43 as monotherapy or in combination with HLX07 in phase 2/3 clinical trial for the treatment of advanced/metastatic squamous non-small cell lung cancer (NSCLC) in Chinese Mainland (International multicentre trial)
HLX43+HLX07+ HANSIZHUANG	Advanced solid tumours	Permitted to commence the phase 1 clinical trial in Chinese Mainland

The complete data of HLX43 in the treatment of non-small cell lung cancer (NSCLC) will be officially presented as a Rapid Oral Presentation at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting which will be held from May 29 to June 2, 2026. The NSCLC data presented at this ASCO Annual Meeting is derived from the pooled analysis of NSCLC patients in the HLX43 first-in-human phase 1 study (HLX43-FIH101) and the global phase 2 study (HLX43-NSCLC201), with efficacy evaluated by a Blinded Independent Central Review (BICR) committee. The abstract for the studies was officially released on May 21 (US Eastern Time). As of December 31, 2025, among the 161 response-evaluable patients (2, 69, 64, 21, and 5 in the 1, 2, 2.5, 3, and 4 mg/kg groups, respectively), the investigator-assessed objective response rate (ORR) was 31.1%. In the 2.0 mg/kg group, investigator-assessed ORR was 36.4% for squamous NSCLC (n=33), among these patients, ORR was 40.0% for those who previously failed docetaxel (n=15). ORR was 47.4%, and 50.0% for patients with EGFR-wildtype (n=19), and EGFR-mutant non squamous (n=16) NSCLC receiving HLX43 at 2.5 mg/kg. Biomarker exploratory analyses showed that efficacy was not associated with PD-L1 expression, with ORRs of 30.1% and 32.1% in patients with PD-L1-positive (n = 83) and PD-L1-negative tumours (n = 78), respectively. The data demonstrate that HLX43 exhibited promising efficacy in patients with heavily pretreated advanced NSCLC, regardless of histology subtypes, brain metastasis and PD-L1 expression, along with manageable tolerability. Further investigation is warranted.

HLX07 is an innovative biologic drug targeting EGFR independently developed by the Company, which is projected to be used for the treatment of advanced solid tumours. In February 2023, the results of the phase 1b/2 clinical study of HLX07 in combination with chemotherapy for the treatment of advanced solid tumours showed that HLX07 was safe and well tolerated. At present, several clinical studies on HLX07 have been commenced in Chinese Mainland, primarily including the phase 2 clinical trial of HLX07 for the monotherapy of advanced cutaneous squamous cell carcinoma (CSCC) and other solid tumours, as well as the international multicentre phase 2/3 clinical trial of HLX07 in combination with HANSIZHUANG and chemotherapy for the treatment of advanced squamous non-small cell lung cancer (NSCLC).

D. MARKET CONDITION

As at the date of this announcement, no similar combination 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 commercialisation of HLX43 and HLX07. 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, 28 May 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.