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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 DOSED IN A PHASE 1B/2 CLINICAL STUDY OF HLX43 FOR INJECTION (AN ANTI-PD-L1 ANTIBODY-DRUG CONJUGATE) IN COMBINATION WITH HLX07 (RECOMBINANT ANTI-EGFR HUMANISED MONOCLONAL ANTIBODY INJECTION) OR HANSIZHUANG (SERPLULIMAB INJECTION) IN PATIENTS WITH ADVANCED OR METASTATIC COLORECTAL CANCER 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 1b/2 clinical study of HLX43 for injection (an anti-PD-L1 antibody-drug conjugate) (“**HLX43**”) in combination with HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection) (“**HLX07**”) or HANSIZHUANG (serplulimab injection) (“**HANSIZHUANG**”) in patients with advanced or metastatic colorectal cancer in Chinese Mainland (excluding Hong Kong, Macau and Taiwan regions of China, same as below).

B. CLINICAL TRIAL DESIGN AND OBJECTIVES

This study is a phase 1b/2 clinical trial evaluating the safety, tolerability, and efficacy of HLX43 in combination with HLX07 or HANSIZHUANG in patients with advanced or metastatic colorectal cancer. The study consists of two parts. Part 1 includes Stage 1 (safety run-in) and Stage 2 (dose expansion). Stage 1 adopts a 3+3 dose-escalation design, in which patients will receive HLX43 at 2.5 mg/kg or 3.0 mg/kg combined with a fixed dose of HLX07 (1000 mg), administered by intravenous infusion once every three weeks (Q3W). The primary objective of Stage 1 is to evaluate the safety and tolerability of different dose levels of HLX43 in combination with HLX07 in patients with advanced or metastatic colorectal cancer. Secondary objectives include assessment of the pharmacokinetic (PK) characteristics and immunogenicity of HLX43, evaluation of efficacy, potential pharmacodynamic effects, and potential predictive or resistance biomarkers. Stage 2 is a randomized, multicentre, open-label study. HLX43 at two dose levels will be expanded in

combination with a fixed dose of HLX07. Based on safety data from the Stage 1, the dose levels of HLX43 are preliminarily set at 2.5 mg/kg and 3.0 mg/kg. The primary objective of Stage 2 is to evaluate the efficacy of different doses of HLX43 in combination with fixed-dose HLX07 in metastatic colorectal cancer (mCRC) patients. Secondary objectives include evaluation of safety and tolerability, the PK characteristics and immunogenicity of HLX43, and potential predictive or resistance biomarkers. Part 2 is a randomized, multicentre, open-label study to evaluate the efficacy and safety of HLX43 at 2.0 mg/kg or 2.5 mg/kg in combination with a fixed dose of HANSIZHUANG (300 mg), Q3W, in patients with mCRC. The primary objective of Part 2 is to assess the efficacy of HLX43 in combination with a fixed dose of HANSIZHUANG in mCRC patients. Secondary objectives include evaluation of safety and tolerability, the PK characteristics and immunogenicity of HLX43, and exploration of potential predictive or resistance biomarkers.

C. ABOUT HLX43, HLX07 AND HANSIZHUANG

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 is as follows:

Product/Combination therapy	Indications	Latest progress
HLX43	Advanced/Metastatic solid tumours	Phase 1 clinical trial in Chinese Mainland (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 trial in Chinese Mainland, the United States, Australia and Japan (international multicentre trial)
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	Phase 1b/2 clinical trial for metastatic colorectal cancer (mCRC) indication in Chinese Mainland
HLX43+HLX07+ HANSIZHUANG	Advanced solid tumours	Permitted to commence the phase 1 clinical trial in Chinese Mainland

The results from the phase 1 clinical trial of HLX43 were released at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting and the 2025 World Conference on Lung Cancer (WCLC), demonstrating good safety and encouraging preliminary efficacy in several solid tumours especially in patients with non-small cell lung cancer (NSCLC). The findings identified HLX43 as a biomarker-independent antibody-drug conjugate (ADC) with immuno-oncology (IO) activity, enabling broad patient coverage. Notably, in patients with NSCLC who had progressed on checkpoint inhibitor (CPI) therapy and chemotherapy, 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%. In addition, the results from the phase 2 clinical trial of HLX43 in recurrent/metastatic cervical cancer (CC) were first presented in Proffered Paper Session at the 2025 European Society for Medical Oncology (ESMO) Asia Congress. The data demonstrated that in patients with recurrent/advanced CC who had previously failed, intolerant to, or contraindicated for standard first-line therapy, HLX43 showed good safety characteristics and exhibited compelling preliminary efficacy. Investigator-assessed ORR was 41.4% in total population and reached 70% in 3.0 mg/kg dose group. The results of a phase 2 clinical trial of HLX43 in recurrent/metastatic esophageal squamous cell carcinoma (ESCC) were first presented at the 2026 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium (ASCO GI). The data demonstrated that in patients with recurrent/advanced ESCC who had failed or were intolerable to standard first-line therapy, HLX43 showed good safety profiles and exhibited promising preliminary efficacy. Investigator-assessed ORR was 30.3% in total population and reached 61.5% in 3.0 mg/kg dose group.

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

HANSIZHUANG is an innovative anti-PD-1 monoclonal antibody independently developed by the Company, which was approved for marketing in Chinese Mainland for indications including the combination with chemotherapy for the first-line treatment of squamous non-small cell lung cancer (sqNSCLC), extensive-stage small cell lung cancer (ES-SCLC), esophageal squamous cell carcinoma (ESCC) and non-squamous non-small cell lung cancer (nsqNSCLC). In December 2025, the New Drug Application (NDA) for HANSIZHUANG in combination with chemotherapy for neo-/adjuvant treatment for gastric cancer has been accepted by the NMPA, and has been granted the procedure for priority review. Meanwhile, HANSIZHUANG was approved for marketing in European Union, United Kingdom, Indonesia, Cambodia, Thailand, Malaysia, Singapore, India and other countries/regions respectively, and has been granted Orphan-drug Designation by drug administrations in the United States, European Union, Switzerland, South Korea and other countries/regions, respectively. In addition, the Company is in the process of advancing a number of clinical studies of HANSIZHUANG and related combination therapies globally, covering a wide range of indications such as lung cancer, esophageal carcinoma, head and neck squamous cell carcinoma, colorectal cancer and gastric cancer.

D. MARKET CONDITION

As at the date of this announcement, no similar combination therapy 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, 11 February 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.