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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

APPLICATION FOR PHASE 1B/2 CLINICAL TRIAL OF HLX43 FOR INJECTION (AN ANTI-PD-L1 ANTIBODY-DRUG CONJUGATE) IN COMBINATION WITH HLX07 (RECOMBINANT ANTI-EGFR HUMANISED MONOCLONAL ANTIBODY INJECTION) FOR THE TREATMENT OF ADVANCED/METASTATIC SOLID TUMOURS WAS APPROVED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

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 application for phase 1b/2 clinical trial of HLX43 for injection (an anti-PD-L1 antibody-drug conjugate) ("**HLX43**") in combination with HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection) ("**HLX07**") for the treatment of advanced/metastatic solid tumours has been approved by the National Medical Products Administration (the "**NMPA**").

B. 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 is 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 trial 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 (mainly including lung cancer population-related data in the whole study) of HLX43 were released at the 2025 World Conference on Lung Cancer (WCLC) ("**2025 WCLC**"). The data demonstrated that in patients with advanced solid 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%. Previously, the relevant data from this phase 1 clinical trial released at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting demonstrated that HLX43 also exhibited encouraging preliminary anti-tumour activity in patients with thymic squamous cell carcinoma (TSCC).

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 phase 2 clinical studies on HLX07 have been commenced in mainland China, primarily include 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 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.

According to the latest updated results released in 2025 WCLC, the combination of HLX07 with serplulimab and chemotherapy demonstrated remarkable antitumor activity and durable efficacy in patients with EGFR overexpression squamous non-small cell lung cancer (sqNSCLC). At a median follow-up of 18.6 months, both dose groups achieved an objective response rate (ORR) of around 70% and a disease control rate (DCR) of over 90%. As of the data cut-off date, the median progression-free survival (PFS) reached 17.4 months in the high-dose group, while the median PFS in the low-dose group could not yet be calculated because most patients remain under stable disease control, demonstrating sustained efficacy, and indicating the combination of anti-EGFR monoclonal antibody and PD-1/L1 inhibitors blocks EGFR signaling while activating immune responses, supporting strong therapeutic synergy.

Preclinical and clinical data indicate that the combination of topoisomerase I inhibitors with anti-EGFR antibodies, as well as the combination of anti-PD-1/PD-L1 antibodies and their corresponding antibody-drug conjugates (ADCs) with EGFR inhibitors, exhibit synergistic efficacy and a favorable safety profile. This combination therapy is expected to provide clinical benefits for patients with advanced solid tumours.

C. 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, 30 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.