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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

THE INVESTIGATIONAL NEW DRUG APPLICATION FOR THE PHASE 1 CLINICAL TRIAL OF HLX37 (RECOMBINANT HUMANISED ANTI-PD-L1 AND ANTI-VEGF BISPECIFIC ANTIBODY) IN COMBINATION WITH CHEMOTHERAPY OR HLX43 FOR INJECTION (AN ANTI-PD-L1 ANTIBODY-DRUG CONJUGATE) FOR THE TREATMENT OF ADVANCED/METASTATIC SOLID TUMOURS HAS BEEN 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 investigational new drug (IND) application for the phase 1 clinical trial of HLX37 (recombinant humanised anti-PD-L1 and anti-VEGF bispecific antibody) (**“HLX37”**), independently developed by the Company, in combination with chemotherapy or HLX43 for injection (an anti-PD-L1 antibody-drug conjugate) (**“HLX43”**), for the treatment of advanced/metastatic solid tumours, has been approved by the National Medical Products Administration (NMPA). The Company intends to commence the relevant clinical trials in Chinese Mainland (excluding Hong Kong, Macau and Taiwan regions of China, the same as below) when the conditions are met.

B. ABOUT HLX37 AND HLX43

HLX37 is a recombinant humanised bispecific antibody targeting PD-L1 and VEGF independently developed by the Company, intended for the treatment of advanced/metastatic solid tumours. HLX37 can act on two different targets simultaneously, and its mechanism of action combines two therapeutic pathways: (1) blocking PD-1/PD-L1 signal pathway: by blocking the binding of PD-L1 on the surface of tumour cells and PD-1 on the surface of T cells, tumour immunosuppression effect is lifted, thereby restoring the ability of T cells to kill tumours; (2) blocking the angiogenesis pathway: by inhibiting the binding of VEGF to its receptor, reducing tumor angiogenesis, thereby limiting tumor growth and metastasis. This dual-target design may produce synergistic antitumor effects and potentially reduce the risk of drug resistance. By specifically binding to PD-L1 on tumour cells, HLX37 achieves enrichment of bispecific molecules within the tumour, resulting in greater efficacy than the combination of anti-PD-L1 monoclonal antibody and anti-VEGF monoclonal antibody. Pre-clinical studies have shown that HLX37 can inhibit tumour growth and has shown favorable safety. In November 2025, the investigational new drug (IND) application for the phase 1 clinical trial of HLX37 in patients with advanced/metastatic solid tumours was approved by the National Medical Products Administration (NMPA). In December 2025, the first patient has been dosed in a phase 1 clinical study of HLX37 in patients with advanced/metastatic solid tumours in Chinese Mainland.

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, 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 the European Union countries (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

Product/Combination therapy	Indications	Latest progress
HLX43+HLX07	Advanced/Metastatic solid tumours	HLX43 in combination with HLX07 or HANSIZHUANG in phase 1b/2 clinical trial for the treatment of advanced/metastatic colorectal cancer (CRC) 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 1b/2 clinical trial in Chinese Mainland
HLX37 in combination with chemotherapy or HLX43	Advanced/Metastatic solid tumours	Permitted to commence the phase 1 clinical trial in Chinese Mainland

C. MARKET CONDITION

As of 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 commercialization of HLX37 and 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, 10 July 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.