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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

ORPHAN-DRUG DESIGNATION OF HLX43 FOR INJECTION (AN ANTI-PD-L1 ANTIBODY-DRUG CONJUGATE) FOR THE TREATMENT OF THYMIC EPITHELIAL TUMOURS (TETS) GRANTED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA)

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 (the "**Board**") of the Company is pleased to announce that, recently, Henlius USA Inc., a wholly-owned subsidiary of the Company, received a letter from the United States Food and Drug Administration ("**FDA**"), granting HLX43 for injection (an anti-PD-L1 antibody-drug conjugate) ("**HLX43**") Orphan-drug Designation for the treatment of thymic epithelial tumours (TETs).

B. 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 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

Product/ Combination therapy	Indications	Latest progress
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
HLX43+HLX07	Advanced/Metastatic solid tumours	Approved to commence the 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). 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).

C. 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.

D. THE IMPACT OF THE DESIGNATION ON THE COMPANY AND THE RISK WARNING

The Orphan-drug Designation granted by the FDA will be beneficial for HLX43 to enjoy certain policy supports in the subsequent R&D, registration and commercialisation in the treatment of thymic epithelial tumours (TETs) in the United States, including but not limited to (1) tax credits for clinical study expenses; (2) exemption from BLA user fees; and (3) seven years of market exclusivity after approval.

If the same drug is approved for the same indication before HLX43 obtains marketing approval for the treatment of thymic epithelial tumours (TETs) from the FDA, HLX43 will have to be demonstrated that it is clinically superior to the already approved same drug in order to obtain policy support for orphan-drug exclusivity.

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. 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, 17 October 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.