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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

HLX43 FOR INJECTION (AN ANTI-PD-L1 ANTIBODY-DRUG CONJUGATE) HAS BEEN APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA) FOR THE PHASE 1 CLINICAL TRIAL FOR THE TREATMENT OF THYMIC CARCINOMA (TC)

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, HLX43 for injection (an anti-PD-L1 antibody-drug conjugate) ("**HLX43**") has been approved by the United States Food and Drug Administration (FDA) to initiate a phase 1 clinical trial for the treatment of thymic carcinoma (TC), enabling the proceeding of subsequent clinical study activities. The Company proposes to commence such clinical study for the treatment of thymic carcinoma (TC) in Australia, Japan, the United States, and other countries when the conditions are met.

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 latest progress of HLX43 and the relevant combination therapies 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) Application for the phase 1 clinical trial was approved in the United States (phase 1 clinical trial for the treatment of thymic carcinoma (TC) has been approved by FDA)

Product/Combination therapy	Indications	Latest progress
HLX43	Advanced non-small cell lung cancer (NSCLC)	Phase 2 clinical trial in mainland China (International multicentre trial) Applications for the phase 2 clinical trials were approved in the United States, Japan, and Australia
HLX43 monotherapy or combination therapy	Advanced/Metastatic solid tumours	Application for the phase 1b/2 clinical trial was approved in mainland China Phase 2 clinical trial of 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

The phase 1 clinical trial results of HLX43 was first released at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting. The data demonstrated that HLX43 has good safety profiles across all dose levels and exhibited encouraging anti-tumour activity in patients with advanced/metastatic solid tumours, particularly in non-small cell lung cancer (NSCLC) and 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.

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, 7 August 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. Yifang Wu, Ms. Xiaohui Guan, Mr. Deyong Wen and Dr. Xingli Wang as the non-executive directors, and Mr. Tak Young So, Dr. Lik Yuen Chan, Dr. Guoping Zhao and Dr. Ruilin Song as the independent non-executive directors.