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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 (ANTIBODY-DRUG CONJUGATE TARGETING PD-L1 WITH NOVEL DNA TOPOISOMERASE I INHIBITOR) FOR THE MONOTHERAPY OR COMBINATION THERAPY OF ADVANCE/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, application for phase 1b/2 clinical trial of HLX43 for injection (antibody-drug conjugate targeting PD-L1 with novel DNA topoisomerase I inhibitor) ("**HLX43**") for the monotherapy or combination therapy of advance/metastatic solid tumours was approved by the National Medical Products Administration (NMPA). The Company intends to conduct clinical trials for the relevant indications of the product in mainland China (excluding Hong Kong, Macau and Taiwan regions, the same below) when the conditions are satisfied.

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 – peptide linker, licensed-in from MediLink Therapeutics (Suzhou) Co., Ltd. in November 2022, with antibody targeting PD-L1 independently developed by the Company, which is designed for the treatment of advance/metastatic solid tumours. HLX43 can specifically bind to human PD-L1 target antigen and release the small-molecule payload in tumour, then kill tumour cells. Non-clinical pharmacology, pharmacokinetics and safety evaluation have proved that HLX43 could inhibit tumour growth and showed a favorable safety profile. In October 2023, application for phase 1 clinical trial of HLX43 for the treatment of advance/metastatic solid tumours was approved by the National Medical Products Administration (NMPA), and the first patient has been dosed in this trial in November 2023 in mainland China. In November 2023, application for phase 1 clinical trial of HLX43 for the treatment of advance/metastatic solid tumours was approved by the United States Food and Drug Administration (FDA).

C. MARKET CONDITION

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 commercialization 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, 4 December 2024

As at the date of this announcement, the board of directors of the Company comprises Mr. Wenjie Zhang as the chairman and 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.