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

HLX42 FOR INJECTION (ANTIBODY-DRUG CONJUGATE TARGETING EGFR WITH NOVEL DNA TOPOISOMERASE I INHIBITOR) HAS BEEN GRANTED THE FAST TRACK DESIGNATION 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 of the Company (the "**Board**") is pleased to announce that, recently, HLX42 for injection (antibody-drug conjugate targeting EGFR with novel DNA topoisomerase I inhibitor) ("**HLX42**") for the treatment of patients with advanced or metastatic EGFR-mutated non-small cell lung cancer whose disease has progressed on a third-generation EGFR tyrosine kinase inhibitor has been granted the Fast Track Designation (the "**FTD**") by the United States Food and Drug Administration (the "**FDA**").

Fast Track is a process designed by FDA to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. Being granted the FTD means HLX42 is eligible to have: (1) more opportunities for meetings and written communication with FDA to obtain closer guidance in drug development, clinical trial design, etc.; (2) eligibility for Accelerated Approval and Priority Review, if relevant criteria are met; and (3) rolling Review, which means that completed sections of Biologic License Application (BLA) or New Drug Application (NDA) can be submitted for review by FDA, rather than waiting until every section is completed before the entire application can be reviewed.

B. ABOUT HLX42

HLX42 is an antibody-drug conjugate (ADC) targeting EGFR 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 monoclonal antibody targeting EGFR independently developed by the Company, which is designed for the treatment of advanced/metastatic solid tumours. HLX42 can specifically bind to human EGFR target antigen and release the small-molecule payload in tumour, then kill tumour cells. Nonclinical pharmacology, pharmacokinetics and safety evaluation have proved that HLX42 could inhibit tumour growth and showed a favorable safety profile. In October 2023 and November 2023, applications for phase 1 clinical trial of HLX42 for the treatment of advanced/metastatic solid tumours were approved by the National Medical Products Administration (NMPA) and FDA, respectively.

C. MARKET CONDITION

As of the date of this announcement, no antibody-drug conjugate targeting EGFR with the small-molecule payload 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 HLX42. 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, 27 December 2023

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