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)
(股份代號: 2696)

VOLUNTARY ANNOUNCEMENT

THE FIRST PATIENT HAS BEEN DOSED IN A PHASE 1 CLINICAL STUDY OF HLX43 FOR INJECTION (ANTIBODY-DRUG CONJUGATE TARGETING PD-L1 WITH NOVEL DNA TOPOISOMERASE I INHIBITOR) IN PATIENTS WITH ADVANCED/METASTATIC SOLID TUMOURS IN MAINLAND CHINA

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 first patient has been dosed in a phase 1 clinical study of HLX43 for injection (antibody-drug conjugate targeting PD-L1 with novel DNA topoisomerase I inhibitor) ("**HLX43**") in patients with advanced/metastatic solid tumours in mainland China (excluding Hong Kong, Macau and Taiwan regions, the same as below).

B. CLINICAL TRIAL DESIGN AND OBJECTIVES

This open-label, dose-escalation, first-in-human phase I clinical trial aims to evaluate the safety and tolerability of HLX43, in patients with advanced/metastatic solid tumours. The study will adopt a "3+3" design with six dose levels planned (0.5 mg/kg, 1 mg/kg, 2 mg/kg, 4 mg/kg, 6 mg/kg, and 8 mg/kg), and patients will receive different doses of HLX43 via intravenous infusion every three weeks. The dose-limiting toxicity (DLT) observation period is three weeks after the first dose of HLX43. The primary endpoints of this study were the proportion of patients with DLT events in each dose group during the DLT observation period, and the maximum tolerated dose (MTD) of HLX43. Secondary endpoints include safety, pharmacokinetic parameters, immunogenicity, preliminary efficacy, pharmacodynamic measures, and potential predictive biomarkers and drug-resistance biomarkers.

C. 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 patients with advanced/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, the application for phase 1 clinical trial of HLX43 for the treatment of advanced/metastatic solid tumours was approved by the National Medical Products Administration.

D. 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, 24 November 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.