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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

THE FIRST PATIENT HAS BEEN DOSED IN A PHASE 1B/2 CLINICAL TRIAL OF HLX43 FOR INJECTION (ANTIBODY-DRUG CONJUGATE TARGETING PD-L1 WITH NOVEL DNA TOPOISOMERASE I INHIBITOR) IN COMBINATION WITH HANSIZHUANG (SERPLULIMAB INJECTION) FOR THE TREATMENT OF 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 1b/2 clinical trial of HLX43 for injection (antibody-drug conjugate targeting PD-L1 with novel DNA topoisomerase I inhibitor) ("**HLX43**") in combination with HANSIZHUANG (serplulimab injection) ("**HANSIZHUANG**") for the treatment of 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 PURPOSE

This phase 1b/2 study aims to evaluate the safety, tolerability, and efficacy of HLX43 in combination with HANSIZHUANG in patients with advanced/metastatic solid tumours. The study is divided into two stages: phase 1b dose escalation and phase 2 dose expansion. The first stage is an open-label study, eligible subjects will receive intravenous infusions of different doses of HLX43 combined with a fixed dose of HANSIZHUANG every three weeks (Q3W). The second stage is a multicenter, randomised, open-label controlled study to evaluate the safety and efficacy of three different doses of HLX43 combined with a fixed dose of HANSIZHUANG in patients with advanced non-small cell lung cancer (NSCLC) based on data from the first stage. The primary endpoints of the first stage are the proportion of subjects experiencing dose-limiting toxicity ("**DLT**") events in each dose group during the DLT observation period and the maximum tolerated dose (MTD) of HLX43 in combination with HANSIZHUANG. The primary endpoint of the second stage is the objective response rate (ORR) assessed by the Independent Radiological Review Committee (IRRC) according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1.

C. ABOUT HLX43 AND HANSIZHUANG

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 advanced/metastatic solid tumours. In October 2023, application for phase 1 clinical trial of HLX43 for the treatment of advanced/metastatic solid tumours was approved by the National Medical Products Administration ("**NMPA**"), and the first patient has been dosed in such trial in November 2023 in mainland China. In November 2023, application for phase 1 clinical trial of HLX43 for the treatment of advanced/metastatic solid tumours was approved by the United States Food and Drug Administration (FDA). In December 2024, application for phase 1b/2 clinical trial of HLX43 for the monotherapy or combination therapy of advanced/metastatic solid tumours was approved by the NMPA, the Company has initiated phase 2 clinical trials of HLX43 in potential solid tumours indications including esophageal squamous cell carcinoma (ESCC). In January 2025, application for phase 1b/2 clinical trial of HLX43 in combination with HANSIZHUANG for the treatment of patients with advanced/metastatic solid tumours was approved by the NMPA.

HANSIZHUANG is an innovative anti-PD-1 monoclonal antibody independently developed by the Company, which was approved for marketing in mainland China for indications including the combination with chemotherapy for the first-line treatment of squamous non-small cell lung cancer (NSCLC), extensive-stage small cell lung cancer (ES-SCLC), esophageal squamous cell carcinoma (ESCC) and non-squamous non-small cell lung cancer (nsNSCLC). Meanwhile, HANSIZHUANG was approved for marketing in the European Union (EU), Indonesia, Cambodia and Thailand, respectively. HANSIZHUANG has been granted orphan-drug designations for the treatment of small cell lung cancer (SCLC) by the United States Food and Drug Administration (FDA) and the European Commission (EC) in April 2022 and December 2022, respectively. In addition, the Company is in the process of advancing a number of clinical studies of HANSIZHUANG and related combination therapies globally, covering a wide range of indications such as lung cancer, esophageal carcinoma, head and neck squamous cell carcinoma, colorectal cancer and gastric cancer.

Both preclinical and clinical data suggest that the combination therapy of Antibody-Drug Conjugates (ADC) and PD-1/L1 monoclonal antibodies can produce a synergistic effect, such combination therapy is expected to provide patients with more effective and safer clinical solutions.

D. MARKET CONDITION

As of the date of this announcement, no similar combination therapy 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, 9 April 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.