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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 AN INTERNATIONAL MULTI-CENTER PHASE 1 CLINICAL STUDY OF A BIOSIMILAR OF PEMBROLIZUMAB HLX17 (RECOMBINANT HUMANISED ANTI-PD-1 MONOCLONAL ANTIBODY INJECTION) IN PATIENTS WITH MULTIPLE RESECTED SOLID TUMOURS IN THE UNITED STATES

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 an international multi-center phase 1 clinical study of a biosimilar of pembrolizumab HLX17 (recombinant humanised anti-PD-1 monoclonal antibody injection) (“**HLX17**”) independently developed by the Company in patients with multiple resected solid tumours in the United States. Such phase 1 clinical study is also being conducted simultaneously in Chinese Mainland (excluding Hong Kong, Macau and Taiwan regions of China, hereinafter the same).

B. CLINICAL TRIAL DESIGN AND OBJECTIVES

This study is a multicenter, randomized, double-blind, parallel-controlled Phase 1 clinical study designed to evaluate the pharmacokinetic (PK) profile, efficacy, safety and immunogenicity of HLX17 vs. US-sourced KEYTRUDA® in patients with multiple resected solid tumours, including non-small cell lung cancer, melanoma, or renal cell carcinoma. Eligible participants will be randomized in a 1:1 ratio to Arm A or Arm B. Participants in Arm A will receive HLX17 (200 mg) by intravenous infusion once every three weeks (Q3W) starting from Cycle 1, and treatment will continue until 12 months after randomization (approximately 17 cycles) or until the occurrence of disease recurrence, death, initiation of new anti-tumour therapy, unacceptable drug toxicity, withdrawal of informed consent, or study termination. Participants in Arm B will receive US-sourced KEYTRUDA® (200 mg) Q3W for the first 8 cycles (24 weeks), after which they will switch to HLX17 200 mg Q3W, and continue treatment until 12 months after randomization or until the discontinuation criteria are met. The primary objective of this study is to evaluate the PK similarity between HLX17 and US-sourced KEYTRUDA® following single and multiple intravenous infusions, with primary endpoints including the area under the serum concentration-time curve from time 0 to 21 days (AUC_{0-21d}) after the 1st dose, and the area under the serum concentration-time curve within a dosing interval at steady state (AUC_{ss}) after the 6th dose. Secondary endpoints include additional PK parameters, efficacy, safety, and immunogenicity.

C. ABOUT HLX17

HLX17 is a biosimilar of pembrolizumab independently developed by the Company, and its potential indications include the indications of the original drug approved such as melanoma, non-small cell lung cancer, esophageal cancer, head and neck squamous cell cancer, colorectal cancer, hepatocellular carcinoma, biliary tract cancer, triple-negative breast cancer, microsatellite instability-high or deficient mismatch repair tumours, gastric cancer, etc. Binding of the PD-1 ligands, PD-L1 and PD-L2, to the PD-1 receptor found on T cells, inhibits T cell proliferation and cytokine production. Upregulation of PD-1 ligands occurs in some tumours and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumours. Pembrolizumab is a monoclonal antibody that binds to the PD-1 receptor and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumour immune response, and increasing the killing capacity of the immune system against tumours. In September 2024, the application for clinical trial of HLX17 was approved by the National Medical Products Administration (NMPA). In September 2025, the investigational new drug (IND) application for the phase 1 clinical trial of HLX17 in patients with multiple resected solid tumours was approved by the United States Food and Drug Administration (FDA). In September 2025, the first patient was dosed in an international multi-center phase 1 clinical study of HLX17 in patients with multiple resected solid tumours in Chinese Mainland.

D. MARKET CONDITION

According to the statistics released by IQVIA MIDAS™ (IQVIA is a global provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry), the sales volume of pembrolizumab worldwide for the year of 2025 was approximately USD35.423 billion.

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 HLX17. 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, 5 June 2026

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. Yuqing Chen, Ms. Xiaohui Guan, Dr. Yi Liu and Dr. Xingli Wang as the non-executive directors, and Mr. Tak Young So, Dr. Lik Yuen Chan, Dr. Ruilin Song and Mr. Yihao Zhang as the independent non-executive directors.