Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.

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 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 an international multi-center phase 1 clinical trial 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 mainland China (excluding Hong Kong, Macau and Taiwan regions of China). The Company also proposes to commence such international multi-center clinical trial in the United States, Europe, Australia and other countries/regions when the conditions are met.

B. CLINICAL TRIAL DESIGN AND PURPOSE

This is a multicenter, randomized, double-blind, parallel-controlled phase 1 study evaluate the similarity of pharmacokinetic profile, efficacy, safety and immunogenicity of HLX17 vs. KEYTRUDA® (US-sourced) in patients with multiple resected solid tumours (including non-small cell lung cancer, melanoma or renal cell carcinoma). Eligible subjects will be randomized in a 1:1 ratio to either Arm A or Arm B, where subjects in Arm A will receive HLX17 once every 3 weeks, and those in Arm B will first receive KEYTRUDA® once every 3 weeks for 8 cycles (24 weeks) before switching to HLX17 treatment, with all subjects continuing treatment until 12 months after the randomization (nearly 17 cycles), investigator-assessed disease recurrence, death, initiation of new anti-tumor therapy, unacceptable toxicity, withdrawal of informed consent, or study termination (whichever occurs first). The primary endpoints of the study are the area under the serum drug concentration-time curve from time 0 to 21 days ($AUC_{0\text{-}21d}$) after the first dose and the area under the serum drug concentration-time curve within a dosing interval at steady state (AUCss) after the sixth dose. Secondary endpoints include other 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).

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 2024 was approximately USD32.056 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, 26 September 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. 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.