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 INVESTIGATIONAL NEW DRUG APPLICATION FOR THE PHASE 1 CLINICAL TRIAL OF HLX48 FOR INJECTION (AN ANTIBODY-DRUG CONJUGATE TARGETING EGFR AND C-MET) FOR THE TREATMENT OF ADVANCED/METASTATIC SOLID TUMORS HAS BEEN APPROVED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

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 investigational new drug application (IND) for the phase 1 clinical trials of HLX48 for injection (an antibody-drug conjugate targeting EGFR and c-MET) ("**HLX48**"), independently developed by the Company for the treatment of advanced/metastatic solid tumors, has been approved by the National Medical Products Administration (NMPA).

B. ABOUT HLX48

HLX48 is a bispecific antibody-drug conjugate (ADC) independently developed by the Company targeting both c-MET and EGFR, planned for the treatment of advanced/metastatic solid tumors. The antibody of HLX48 binds to tumor cells expressing c-MET/EGFR and induces receptor-mediated endocytosis into the tumor cells, releasing payload that cause DNA damage and cell death, while also killing adjacent tumor cells through the bystander effect of the payload. In addition, the variable region of the HLX48 antibody specifically binds to tumor cells expressing c-MET/EGFR, blocking the binding of ligands Epidermal Growth Factor (EGF)/Hepatocyte Growth Factor (HGF) to their respective receptors, thereby inhibiting the activation of downstream signaling pathways, and exerting antibody-dependent cell-mediated cytotoxicity (ADCC) through the Fragment crystallizable (Fc) region. Therefore, HLX48 is expected to exert synergistic effects through both targeted therapy and immune modulation, thereby inhibiting tumor growth with a favorable safety profile. Preclinical studies have demonstrated that HLX48 exhibits good anti-tumor efficacy and safety, and is expected to provide clinical benefits. In May 2026, the phase 1 clinical trial of HLX48 for the treatment of advanced/metastatic solid tumors has been approved by the relevant Human Research Ethics Committee and acknowledged by the Therapeutic Goods Administration (TGA) of Australia.

C. MARKET CONDITION

As of the date of this announcement, no bispecific antibody-drug conjugate targeting EGFR and c-MET 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 HLX48. 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, 21 May 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.