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

FIRST PATIENT HAS BEEN DOSED IN THE PHASE 2/3 CLINICAL STUDY OF HLX22 (RECOMBINANT HUMANISED ANTI-HER2 MONOCLONAL ANTIBODY INJECTION) IN COMBINATION WITH HLX87 FOR INJECTION (ANTIBODY-DRUG CONJUGATE TARGETING HER2) FOR FIRST-LINE TREATMENT OF PATIENTS WITH HER2-POSITIVE RECURRENT OR METASTATIC BREAST CANCER (BC) IN CHINESE MAINLAND

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 2/3 clinical study of HLX22 (recombinant humanised anti-HER2 monoclonal antibody injection) ("**HLX22**") in combination with HLX87 for injection (antibody-drug conjugate targeting HER2) ("**HLX87**") for first-line treatment of patients with HER2-positive recurrent or metastatic breast cancer (BC) in Chinese Mainland (excluding Hong Kong, Macau and Taiwan regions of China, same as below).

B. CLINICAL TRIAL DESIGN AND OBJECTIVES

This study is an open-label, randomised, multicenter phase 2/3 clinical study to evaluate HLX22 in combination with HLX87 for the first-line treatment of patients with HER2-positive recurrent or metastatic breast cancer. The study includes two stages, the first stage is an open-label, multicenter, randomised, parallel-controlled phase 2 study. Eligible subjects will be randomised at a ratio of 2:2:1:1 to receive HLX22 in combination with HLX87, Pertuzumab in combination with HLX87, Pertuzumab in combination with Trastuzumab deruxtecan, or Pertuzumab in combination with Trastuzumab and Docetaxel.

The primary endpoints of the first stage are the Objective Response Rate (ORR) and Progression-Free Survival ("**PFS**") assessed by the Blinded Independent Central Review ("**BICR**"). The second stage is an open-label, multicenter, randomised, parallel-controlled phase 3 study. Eligible subjects will be randomised at a ratio of 1:1 to receive HLX22 in combination with HLX87 or Pertuzumab in combination with Trastuzumab and Docetaxel. The primary endpoint of the second stage is PFS assessed by BICR. The primary objective of the study is to evaluate clinical efficacy of HLX22 in combination with HLX87 for the first-line treatment of patients with HER2-positive recurrent or metastatic breast cancer. The secondary objectives include evaluating safety, tolerability, pharmacokinetic (PK) characteristics and immunogenicity, exploring potential predictive or resistance biomarkers.

C. ABOUT HLX22 AND HLX87

HLX22 is a license-in innovative anti-HER2 monoclonal antibody subsequently self-developed by the Company with potential indications including gastric cancer, breast cancer and other solid tumours. HLX22 has been granted Orphan-drug Designation for the treatment of gastric cancer by the United States Food and Drug Administration (FDA) and the European Commission (EC) in March 2025 and May 2025, respectively. As of the date of this announcement, the latest development progress of HLX22 is as follows:

Products/Combination therapy	**Indications**	**Latest progress**
HLX22 + standard therapy (Trastuzumab + chemotherapy)	HER2-positive locally advanced or metastatic gastroesophageal junction cancer and gastric cancer	Phase 3 clinical trial in Chinese Mainland, the United States, EU countries, Australia, Japan and other countries/regions (international multi-center trial)
HLX22+HLX87	HER2-positive breast cancer	Phase 2/3 clinical trial in Chinese Mainland
	neoadjuvant treatment for HER2-positive breast cancer	Application for the phase 2/3 clinical trial was approved in Chinese Mainland
HLX22 + standard therapy/ HLX22 + Trastuzumab deruxtecan	HER2-low, HR-positive locally advanced or metastatic breast cancer	Phase 2 clinical trial in Chinese Mainland
HLX22 + HANSIZHUANG + standard therapy (Trastuzumab + chemotherapy)	HER2-positive locally advanced/metastatic gastric cancer	Application for the phase 2 clinical trial was approved in Chinese Mainland

HLX87 is an innovative HER2-targeted antibody-drug conjugate (ADC) licensed from GeneQuantum Healthcare (Suzhou) Co., Ltd. by the Company. The drug conjugates a topoisomerase I inhibitor payload to an anti-HER2 monoclonal antibody via a stable, cleavable open-chain linker, currently in phase 3 clinical development, with potential indications including the treatment of HER2-positive breast cancer, etc. According to the licensing arrangement, the Company obtained certain rights with respect to the development and commercialisation of HLX87 in Chinese Mainland and certain designated countries and regions. Featuring a highly membrane-permeable topoisomerase inhibitor payload, HLX87 delivers potent bystander killing effects while minimizing systemic toxicity through its unique and stable linker design, achieving an optimal balance between efficacy and safety. Preclinical studies demonstrated comparable antitumor efficacy to trastuzumab deruxtecan (T-DXd) in multiple xenograft models, with a superior safety profile. According to the Phase 1 clinical data of HLX87 in HER2-expressing or HER2-mutated advanced solid tumors presented at the 2024 American Association for Cancer Research Annual Meeting (AACR 2024), the results showed favorable tolerability and safety across doses ranging from 2.0 mg/kg to 8.4 mg/kg, along with promising efficacy in patients with breast, gastric, and lung cancers.

In December 2025, the applications for phase 2/3 clinical trials of HLX22 in combination with HLX87 for injection (1) for first-line treatment of HER2-positive breast cancer (BC); and (2) for neoadjuvant treatment for HER2-positive breast cancer (BC neo) were approved by the National Medical Products Administration (NMPA), respectively.

D. MARKET CONDITION

As at the date of this announcement, no similar combination has been approved for marketing in Chinese Mainland.

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 commercialisation of HLX22 and HLX87. 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, 27 February 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.