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

APPLICATIONS FOR PHASE 2/3 CLINICAL TRIALS 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 HER2-POSITIVE BREAST CANCER (BC) AND NEOADJUVANT TREATMENT FOR HER2-POSITIVE BREAST CANCER (BC NEO) WERE 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 applications for phase 2/3 clinical trials of HLX22 (recombinant humanised anti-HER2 monoclonal antibody injection) ("**HLX22**") in combination with HLX87 for injection (antibody-drug conjugate targeting HER2) ("**HLX87**") (1) for first-line treatment of HER2-positive breast cancer (BC); and (2) for neoadjuvant treatment for HER2-positive breast cancer (BC neo) have been approved by the National Medical Products Administration (NMPA), respectively. The Company proposes to commence relevant clinical trials in Chinese Mainland when the conditions are met.

B. 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	Application for the phase 2/3 clinical trial was approved 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). 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. 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. Currently, a phase 3 clinical trial of HLX87 for the second-line treatment of HER2-positive breast cancer is underway in the Chinese Mainland. Previously, the Company entered into a strategic collaboration with an external partner regarding the in-licensing of HLX87. The specific cooperation arrangements and implementation will be subject to the transaction arrangements stipulated in the definitive license agreement to be signed by both parties in the future.

C. MARKET CONDITION

As at the date of this announcement, no similar combination 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 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, 9 December 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.