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

APPLICATION FOR THE PHASE 3 CLINICAL TRIAL OF HLX22 (ANTI-HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR-2 (HER2) HUMANIZED MONOCLONAL ANTIBODY INJECTION) IN COMBINATION WITH TRASTUZUMAB AND CHEMOTHERAPY AS THE FIRST-LINE TREATMENT OF HER2 POSITIVE ADVANCED GASTRIC CANCER APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA)

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, application for the phase 3 clinical trial of HLX22 (anti-human epidermal growth factor receptor-2 (HER2) humanized monoclonal antibody injection) ("**HLX22**") in combination with Trastuzumab and chemotherapy as the first-line treatment of HER2 positive advanced gastric cancer has been approved by the United States Food and Drug Administration (FDA).

B. ABOUT HLX22

HLX22 is an innovative anti-HER2 monoclonal antibody introduced from AbClon, Inc. and subsequently self-developed by the Company with potential indications including gastric cancer, breast cancer and other solid tumours, which has completed the phase 1 clinical trial for the treatment of HER2 overexpressing advanced solid tumors in mainland China (excluding Hong Kong, Macau and Taiwan regions, the same as below). Both HLX22 and

Trastuzumab are anti-HER2 monoclonal antibodies that bind to the domain IV of HER2, but the epitopes they bind to are different, which allows HLX22 and Trastuzumab to simultaneously bind to the domain IV of HER2 to induce stronger HER2 receptor blockade. Results of pre-clinical studies indicate that the combination of HLX22 and Trastuzumab has a synergistic anti-tumor effect, better than HLX22 or Trastuzumab as a single antibody. As of the date of this announcement, a phase 2 clinical trial of HLX22 in combination with Trastuzumab and chemotherapy as the first-line treatment of HER2-positive locally advanced/metastatic gastric cancer (GC) is underway in mainland China. In October 2022, the application for the phase 2 clinical trial of HLX22 in combination with HANSIZHUANG (serplulimab injection) and the standard therapy (Trastuzumab and chemotherapy) as the first-line treatment for locally advanced/ metastatic gastric cancer (GC) has been approved by the National Medical Products Administration.

C. MARKET CONDITION

As of the date of this announcement, no marketing approval has been obtained for similar combination therapy for the treatment of gastric cancer worldwide.

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 HLX22. 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, 6 May 2024

As at the date of this announcement, the board of directors of the Company comprises Mr. Wenjie Zhang as the chairman and executive director, Mr. Jun Zhu as the executive director, Mr. Qiyu Chen, Mr. Yifang Wu, Ms. Xiaohui Guan, Mr. Deyong Wen and Dr. Xingli Wang as the non-executive directors, and Mr. Tak Young So, Dr. Lik Yuen Chan, Dr. Guoping Zhao and Dr. Ruilin Song as the independent non-executive directors.