**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 3 CLINICAL STUDY OF HLX22 (RECOMBINANT HUMANIZED ANTI-HER2 MONOCLONAL ANTIBODY INJECTION) IN COMBINATION WITH TRASTUZUMAB AND CHEMOTHERAPY (XELOX) VERSUS TRASTUZUMAB AND CHEMOTHERAPY (XELOX) WITH OR WITHOUT PEMBROLIZUMAB FOR THE FIRST-LINE TREATMENT OF LOCALLY ADVANCED OR METASTATIC GASTROESOPHAGEAL JUNCTION AND GASTRIC CANCER 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 3 clinical study of HLX22 (recombinant humanized anti-HER2 monoclonal antibody injection) ("**HLX22**") in combination with Trastuzumab and chemotherapy (XELOX) versus Trastuzumab and chemotherapy (XELOX) with or without pembrolizumab for the first-line treatment of locally advanced or metastatic gastroesophageal junction and gastric cancer in mainland China (excluding Hong Kong, Macau and Taiwan regions, the same as below).

## B. CLINICAL TRIAL DESIGN AND OBJECTIVES

This double-blind, randomized, controlled multicenter phase 3 study aims to compare the efficacy and safety of HLX22 in combination with Trastuzumab and chemotherapy versus Trastuzumab and chemotherapy with or without pembrolizumab as first-line treatment in patients with human epidermal growth factor receptor 2 (HER2)-positive, locally advanced or metastatic gastric/gastroesophageal junction cancer. Eligible participants will be randomized at 1:1 to the experimental arm (treated with HLX22 (15 mg/kg) in combination with Trastuzumab and chemotherapy) or the control group (placebo plus Trastuzumab and chemotherapy with or without pembrolizumab). The primary endpoints of this study are progression-free survival (PFS) assessed by independent radiology review committee (IRRC) per RECIST v1.1 and overall survival (OS), the secondary endpoints include investigator-assessed PFS, IRRC or investigator-assessed objective response rate (ORR), PFS2, duration of response (DOR), quality of life, safety, immunogenicity, and pharmacokinetic characteristics.

## C. 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 tumors, which has completed the phase 1 clinical trial for the treatment of HER2 overexpressing advanced solid tumors in mainland China. Both HLX22 and Trastuzumab are anti-HER2 monoclonal antibodies that bind to the subdomain 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 May 2024, the application for the phase 3 clinical trial of HLX22 in combination with Trastuzumab and chemotherapy as the first-line treatment of HER2 positive locally advanced or metastatic gastric/gastroesophageal junction cancer has been approved by the United States Food and Drug Administration (FDA). In October 2024, the application for the phase 3 clinical trial of HLX22 in combination with Trastuzumab and chemotherapy as the first-line treatment of HER2 positive locally advanced or metastatic gastric/gastroesophageal junction cancer has been granted an implied license by the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan.

## D. MARKET CONDITION

As of the date of this announcement, no marketing approval has been obtained for similar combination therapy for the treatment of gastric/gastroesophageal junction 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, 22 November 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, Dr. 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.*