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

NEW DRUG APPLICATION (NDA) FOR PERTUZUMAB BIOSIMILAR HLX11 (RECOMBINANT ANTI-HER2 DOMAIN II HUMANIZED MONOCLONAL ANTIBODY INJECTION) HAS BEEN ACCEPTED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION (NMPA)

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 (the "**Board**") of the Company is pleased to announce that, recently, the New Drug Application ("**NDA**") for HLX11, a proposed pertuzumab biosimilar (recombinant anti-HER2 domain II humanized monoclonal antibody injection) ("**HLX11**") independently developed by the Company, has been accepted by the Center for Drug Evaluation of the National Medical Products Administration ("**NMPA**"). The indications involved in this NDA include: use in combination with trastuzumab and chemotherapy as adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence; and use in combination with trastuzumab and docetaxel for treatment of patients with HER2-positive, metastatic or unresectable local recurrent breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

B. BACKGROUND OF AND BASIS FOR SUBMISSION

HLX11, which was independently developed by the Company, is a proposed biosimilar to pertuzumab. It may be intended for use in combination with trastuzumab and chemotherapy as adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence; and use in combination with trastuzumab and docetaxel for treatment of patients with HER2-positive, metastatic or unresectable local recurrent breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease. In November 2021, the phase 1 clinical trial of HLX11 was successfully completed in mainland China (excluding Hong Kong, Macau and Taiwan regions, the same as below). In September 2024, an international multi-center phase 3 clinical study of HLX11 for the neoadjuvant therapy of HER2-positive, HR-negative early or locally advanced breast cancer had met the primary study endpoint.

The new drug application was based on the data generated by HLX11 in comparison with the reference drug Perjeta®, which includes analytical studies of similarities and clinical comparison studies. These data demonstrated that HLX11 is highly similar to the reference drug Perjeta® in terms of quality, safety and efficacy.

C. MARKET CONDITION

As of the date of this announcement, pertuzumab injection marketed in mainland China is Perjeta® (帕捷特®) of the Roche Group. According to the data from IQVIA CHPA (provided by IQVIA, which is a global provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry), the sales value of pertuzumab injection products in mainland China for the year of 2023 was approximately RMB3.387 billion.

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 HLX11. 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, 4 December 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.