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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 SUBJECT HAS BEEN DOSED IN A PHASE 1 CLINICAL STUDY OF PERTUZUMAB AND TRASTUZUMAB INJECTION (SUBCUTANEOUS INJECTION) BIOSIMILAR HLX319 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 subject has been dosed in the phase 1 clinical study of pertuzumab and trastuzumab injection (subcutaneous injection) biosimilar HLX319 (“**HLX319**”) independently developed by the Company in Chinese Mainland (excluding Hong Kong, Macau and Taiwan regions of China).

B. CLINICAL TRIAL DESIGN AND OBJECTIVES

This study is a randomized, double-blind, single-dose subcutaneous administration, parallel-controlled phase 1 clinical trial aimed at evaluating the pharmacokinetic (PK) characteristics, safety, tolerability, and immunogenicity of HLX319 and its reference product Phesgo® (commercially available in Europe) in healthy Chinese male subjects. Eligible subjects will be randomized in a 1:1 ratio into two groups to receive either HLX319 or Phesgo® as a single-dose, single-administration subcutaneous injection. The injection will be administered into the subcutaneous tissue of the thigh over approximately 5 minutes. The primary endpoints of this study are the key PK parameters of pertuzumab and trastuzumab, including maximum concentration (C_{max}) and area under the serum concentration-time curve from time zero to infinity ($AUC_{0-\infty}$). Secondary endpoints include other PK parameters, safety endpoints, and immunogenicity endpoints.

C. ABOUT HLX319

HLX319 is a biosimilar of pertuzumab and trastuzumab injection (subcutaneous injection) independently developed by the Company, which contains the active ingredients trastuzumab and pertuzumab, and the excipient hyaluronidase (HLXTE-HAase02, a novel recombinant human hyaluronidase independently developed by the Company), intended for the adjuvant/neoadjuvant treatment of early-stage or locally advanced HER2-positive breast cancer and treatment of metastatic breast cancer. Pertuzumab and trastuzumab injection (subcutaneous injection) is a fixed-dose combination formulation for subcutaneous administration comprising trastuzumab and pertuzumab, which can target different epitopes of HER2 to synergistically block HER2 signaling and mediate antibody-dependent cellular cytotoxicity (ADCC), thereby exerting antitumor effects. In particular, trastuzumab can specifically bind to the extracellular domain IV of HER2, blocking receptor signal transduction and inhibiting tumor cell proliferation, while mediating ADCC. Pertuzumab can specifically bind to the extracellular domain II of HER2, blocking the ligand dimerization of HER2 with other members of the ErbB family, thereby leading to cell growth arrest and apoptosis, while mediating ADCC. In accordance with the requirements of guidance on biosimilar issued by the National Medical Products Administration (NMPA), and with reference to the EU guidance on biosimilar, the preclinical pharmacodynamic, pharmacokinetic and toxicological comparative studies have demonstrated that HLX319 is similar to the original pertuzumab and trastuzumab injection (subcutaneous injection). In March 2026, the investigational new drug applications (INDs) for the phase 1 clinical trial of HLX319 were approved by the National Medical Products Administration (NMPA).

D. MARKET CONDITION

According to the statistics released by IQVIA MIDAS™ (IQVIA is a global provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry), the sales revenue of pertuzumab and trastuzumab injection (subcutaneous injection) worldwide for the year of 2025 was approximately USD3.023 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 commercialization of HLX319. 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, 10 April 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.