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 PHASE 1 CLINICAL STUDY OF A BIOSIMILAR OF DARATUMUMAB HLX15 (RECOMBINANT ANTI-CD38 HUMAN MONOCLONAL ANTIBODY INJECTION) SUCCESSFULLY COMPLETED

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, a phase 1 clinical study of a biosimilar of daratumumab HLX15 (recombinant anti-CD38 human monoclonal antibody injection) ("**HLX15**") independently developed by the Company in healthy Chinese male subjects, has been successfully completed. The results of this study demonstrated that HLX15 had similar pharmacokinetic characteristics, as well as comparable safety and immunogenicity profiles to daratumumab sourced from different regions. This study met all of the pre-specified endpoints.

B. DESIGN, PURPOSE AND CONCLUSION OF THE CLINICAL TRIAL

This phase 1 study aimed to compare the pharmacokinetic characteristics, safety, tolerability, and immunogenicity of HLX15 and daratumumab in healthy Chinese male subjects. This study consisted of two parts. Part 1 was a single-centre, randomised, open-label, two-arm, parallel-controlled phase 1a study, in which subjects were randomised 1:1 to receive HLX15 or daratumumab sourced from China (8 mg/kg, single dose, intravenous infusion). Part 2 was a multicentre, randomised, double-blind, four-arm, parallel-controlled phase 1b study, in which subjects were randomised 1:1:1:1 to receive HLX15 or daratumumab sourced from the United States, European Union, or China (8 mg/kg, single dose, intravenous infusion). The primary endpoint was the area under the serum drug concentration-time curve from time 0 to infinity ($AUC_{0\text{-}inf}$). Secondary endpoints included other pharmacokinetic parameters, safety, and immunogenicity. The results of this study demonstrated that HLX15 had similar pharmacokinetic characteristics, as well as comparable safety and immunogenicity profiles to daratumumab sourced from different regions. This study met all of the pre-specified endpoints.

C. ABOUT HLX15

HLX15 is a biosimilar of daratumumab developed by the Company independently, which is intended for the treatment of multiple myeloma ("**MM**"). Daratumumab is a humanized anti-CD38 IgG1κ monoclonal antibody, which can bind CD38 expressed on the surface of tumor cells and induce tumor apoptosis through complement-dependent cytotoxicity (CDC), antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP), and several immune-related mechanisms such as Fcγ receptors. In addition, daratumumab can also reduce MM cells by reducing myeloid-derived suppressor cells and depleting CD38-positive immunomodulatory T and B cells. According to the Technical Guidelines for R&D and Evaluation of Biosimilars (Trial), the Company has conducted a comprehensive head-to-head comparison study of HLX15 and the original drug daratumumab injection in pharmacy and in vitro and in vivo pharmacology. The results of the study showed that HLX15 is highly similar to daratumumab injection.

D. MARKET CONDITION

As at the date of this announcement, the daratumumab commercially available in mainland China (excluding Hong Kong, Macao and Taiwan regions, the same below) include Zhaoke (兆珂®) (a daratumumab injection) and Zhaokesu (兆珂速®) (a daratumumab subcutaneous injection) of Johnson & Johnson. According to the information of IQVIA CHPA and IQVIA MIDAS™ (IQVIA is a global provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry), the sales volume of daratumumab in mainland China and worldwide for the year of 2023 was approximately RMB852 million and US$5.254 billion, respectively.

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 HLX15. 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, 28 June 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.