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 MULTICENTER PHASE 1 CLINICAL STUDY OF HLX15-SC (RECOMBINANT ANTI-CD38 FULLY HUMAN MONOCLONAL ANTIBODY INJECTION-SUBCUTANEOUS INJECTION) FOR FIRST-LINE TREATMENT OF NEWLY DIAGNOSED MULTIPLE MYELOMA (NDMM) 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 patient has been dosed in an international multicenter phase 1 clinical study of HLX15-SC (recombinant anti-CD38 fully human monoclonal antibody injection-subcutaneous injection) ("**HLX15-SC**") for first-line treatment of newly diagnosed multiple myeloma (NDMM) in Chinese Mainland (excluding Hong Kong, Macau and Taiwan regions of China).

B. CLINICAL TRIAL DESIGN AND OBJECTIVES

This study is a multicenter, randomized, double-blind, parallel-controlled phase 1 trial in transplant-ineligible patients with newly diagnosed multiple myeloma, aiming to compare the pharmacokinetic (PK) similarity, safety, tolerability, and immunogenicity of HLX15-SC versus the US-licensed DARZALEX FASPRO® (US-DARZALEX FASPRO®), each in combination with lenalidomide and dexamethasone (Rd). Eligible subjects will be randomized in a 1:1 ratio to either the HLX15-SC-Rd group or the US-DARZALEX FASPRO®-Rd group. Participants will receive 1800 mg of HLX15-SC or US-DARZALEX FASPRO® by subcutaneous (SC) injection through Week 16. Thereafter, based on clinical benefit and other considerations, subjects may continue treatment with locally marketed subcutaneous daratumumab in combination with Rd through Week 32. After that, participants will receive appropriate standard-of-care treatment according to local guidelines. The primary objective of this study is to evaluate the PK similarity of HLX15-SC and the reference product after single and multiple SC injections in the target patient population. The secondary objective is to compare the PK characteristics, safety, tolerability, immunogenicity, and efficacy of HLX15-SC and the reference product following single and multiple SC injections.

C. ABOUT HLX15

HLX15 (recombinant anti-CD38 fully human monoclonal antibody) ("**HLX15**") is a biosimilar of daratumumab developed by the Company independently, which is intended for the treatment of multiple myeloma ("**MM**") and other indications. 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. In June 2024, the phase 1 clinical study of HLX15-IV (intravenous injection) in healthy Chinese male subjects has been successfully completed. In February 2026, the investigational new drug (IND) applications for phase 1 clinical trial of HLX15-SC for the treatment of multiple myeloma were approved by the National Medical Products Administration (NMPA) and the United States Food and Drug Administration (FDA), respectively.

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 daratumumab worldwide for the year of 2025 was approximately US$16.013 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 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, 26 May 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.