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 DENOSUMAB HLX14 (RECOMBINANT ANTI-RANKL 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 denosumab HLX14 (recombinant anti-RANKL human monoclonal antibody injection) ("**HLX14**") independently developed by the Company in Chinese healthy adult male subjects, has been successfully completed. The results of the study suggest that HLX14 had highly similar pharmacokinetics (PK) and pharmacodynamics (PD), as well as comparable safety, tolerability, and immunogenicity to the reference drugs (defined as follows) from different sources. This study met all of the pre-specified endpoints.

B. DESIGN, PURPOSE AND CONCLUSION OF THE CLINICAL TRIAL

This is a two-part phase 1 clinical study in Chinese healthy adult male subjects. Part 1 is an open-label, randomised, parallel-controlled, single-dose, two-arm pilot study with the primary objective to compare the PK parameters of HLX14 and EU-sourced denosumab after subcutaneous injection, to provide further basis for the study design of part 2. The secondary objective of part 1 is to compare the PD, safety, tolerability, and immunogenicity of HLX14 and EU-sourced denosumab. Part 2 is a double-blind, randomised, parallel-controlled, single-dose, four-arm study with the primary objective to compare the PK similarity of HLX14 with US-, EU-, and CN-sourced denosumab ("**reference drug**"). The secondary objective of part 2 is to compare PD, safety, tolerability, and immunogenicity between HLX14 and the reference drugs. The results of the study suggest that HLX14 had highly similar PK and PD to the reference drugs from different sources, with geometric mean ratios (GMRs) of primary PK endpoints near 1 and their 90% confidence intervals (CIs) falling entirely in pre-specified equivalence margins of 0.8 to 1.25. Safety, tolerability, and immunogenicity were also comparable. This study met all of the pre-specified endpoints.

C. INFORMATION ABOUT HLX14

HLX14, which was independently developed by the Company, is a biosimilar of denosumab injection. It is intended for the treatment of osteoporosis in postmenopausal women at high risk for fracture and/or for other indications consistent with the label of the original biologics. Currently, denosumab, the original biologic of HLX14, has been approved in different countries for a range of indications such as for the treatment of osteoporosis in postmenopausal women at high risk for fracture, osteoporosis in men at high risk for fracture, bone loss in specific populations at high risk for fracture, prevention of skeletal-related events in patients with bone metastases from solid tumours and in patients with multiple myeloma, and the treatment of giant cell tumour of bone and hypercalcemia of malignancy, etc. In June 2022, the Company entered into an agreement with Organon LLC, pursuant to which, the Company agreed to grant an exclusive license to Organon LLC and its affiliates to commercialise HLX14 globally except for mainland China, Hong Kong, Macau and Taiwan regions. In the same month, the first patient has been dosed in an international multi-centre phase 3 clinical trial of HLX14 for the treatment of osteoporosis in postmenopausal women at high risk for fracture in mainland China. The study is currently underway.

D. MARKET CONDITION

As of the date of this announcement, denosumab injections marketed in mainland China include XGEVA® and Prolia® of Amgen Inc. approved for different indications under different trade names, and Boyoubei® of Shandong Boan Biotechnology Co., Ltd. Denosumab injections marketed globally include Prolia® of Amgen Inc., Pralia® of Daiichi Sankyo Company Limited and Rozel® of Intas Pharmaceuticals Ltd. 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 denosumab injection in mainland China and worldwide for the year of 2022 was approximately RMB477 million and US$6.222 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 commercialisation of HLX14. 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, 1 February 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.