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

AN INTERNATIONAL MULTI-CENTRE PHASE 3 CLINICAL STUDY OF A BIOSIMILAR OF DENOSUMAB HLX14 (RECOMBINANT ANTI-RANKL HUMAN MONOCLONAL ANTIBODY INJECTION) FOR THE TREATMENT OF OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN AT HIGH RISK FOR FRACTURE HAS MET THE PRIMARY STUDY ENDPOINTS

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, an international multi-centre phase 3 clinical study of a biosimilar of denosumab HLX14 (recombinant anti-RANKL human monoclonal antibody injection) ("**HLX14**") independently developed by the Company for the treatment of osteoporosis in postmenopausal women at high risk for fracture has met the primary study endpoints.

B. DESIGN, PURPOSE AND CONCLUSION OF THE CLINICAL TRIAL

This randomised, double-blind, international multicentre, parallel-controlled phase 3 clinical study aimed to compare the efficacy, safety, tolerability, and immunogenicity of HLX14 with reference denosumab (Prolia®) in postmenopausal women subjects with osteoporosis at high risk of fracture. Eligible subjects were randomised into two groups at a ratio of 1:1 to receive subcutaneous injection of 60 mg of HLX14 or reference denosumab (Prolia®) every six months. The primary endpoints of this study were the percentage change in bone mineral density (BMD) at the lumbar spine from baseline to Week 52 (D365) assessed by central imaging, and the area under the effect-time curve for percentage change of serum collagen C-telopeptide (s-CTX) from baseline to Week 26 (D183) ($AUEC_{0\text{-}26W}$). The secondary endpoints included other efficacy measures and pharmacodynamic characteristics, as well as the incidence of intercurrent events, safety, pharmacokinetic characteristics, and immunogenicity. The primary endpoints of this study were met.

C. INFORMATION ABOUT HLX14

HLX14, which was independently developed by the Company, is a proposed biosimilar to denosumab. 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 and regions under different trade names for a range of different indications such as for the treatment of osteoporosis in postmenopausal women at high risk for fracture, among others. In June 2022, the Company entered into an agreement with Organon LLC (a wholly-owned subsidiary of Organon & Co.,), pursuant to which, the Company agreed to grant an exclusive license to Organon and its affiliates to commercialise HLX14 globally except for mainland China, Hong Kong, Macau and Taiwan regions. In January 2024, a phase 1 clinical study of HLX14 in Chinese healthy adult male subjects was successfully completed.

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 value of denosumab injections 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, 5 April 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.