Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.

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

MARKETING AUTHORIZATION APPLICATIONS (MAAs) FOR BIOSIMILAR OF DENOSUMAB HLX14 (RECOMBINANT ANTI-RANKL HUMAN MONOCLONAL ANTIBODY INJECTION) VALIDATED BY THE EUROPEAN MEDICINES AGENCY (EMA)

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, two marketing authorization applications (MAAs) for the Prolia® and Xgeva® (denosumab) biosimilar, HLX14 (recombinant anti-RANKL human monoclonal antibody injection) ("**HLX14**") independently developed by the Company have been validated by the European Medicines Agency (EMA).

The indications of the two marketing authorization applications (MAAs) are identical to those of Prolia® and Xgeva® (denosumab) approved for market by the European Union, including: (1) treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures, (2) treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures, (3) treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture, (4) prevention of skeletal related events in adults with advanced malignancies involving bone, and (5) treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity.

B. BACKGROUND OF AND BASIS FOR SUBMISSION

HLX14, which was independently developed by the Company, is a proposed biosimilar to Prolia® and Xgeva® (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 reference biologic. Currently, denosumab, the reference 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 granted 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, the phase 1 clinical study of HLX14 in Chinese healthy adult male subjects was successfully completed. In April 2024, the international multi-centre phase 3 clinical study of HLX14 for the treatment of osteoporosis in postmenopausal women at high risk for fracture met the primary study endpoints.

The submission is based on data generated with HLX14 versus reference denosumab (Prolia®), including analytical similarity and clinical comparative studies. CHMP Guideline on similar biological medicinal products (CHMP/437/04 Rev1) allows for extrapolation of clinical safety and efficacy data to other approved indications of a reference drug.

C. MARKET CONDITION

As of the date of this announcement, denosumab injections marketed globally include Prolia® and Xgeva® of Amgen Inc. approved for different indications under different trade names, 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 worldwide for the year of 2023 was US$6.83 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 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, 24 May 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.