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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

BIOSIMILAR OF DENOSUMAB HLX14 (RECOMBINANT ANTI-RANKL HUMAN MONOCLONAL ANTIBODY INJECTION) RECEIVED POSITIVE OPINION FROM THE COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP) OF 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.

Reference is made to the announcement of the Company dated 24 May 2024 in relation to that the two marketing authorisation applications (MAAs) for the Prolia® (denosumab) and Xgeva® (denosumab) biosimilar, HLX14 (recombinant anti-RANKL human monoclonal antibody injection) ("**HLX14**") independently developed by the Company for the (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, and/or for other indications consistent with the labels of the reference biologics have been validated by the European Medicines Agency ("**EMA**").

The board of directors of the Company (the "**Board**") is pleased to announce that, recently, HLX14 received positive opinions from the Committee for Medicinal Products for Human Use ("**CHMP**") of the EMA, recommending the approval of HLX14. The opinions from CHMP will be submitted to the European Commission ("**EC**"), then the EC will issue final review decisions based on such opinion within the next two to three months. Once approved by the EC, centralized marketing authorisations in respect of HLX14 will be valid in all EU Member States as well as European Economic Area (EEA) countries Iceland, Liechtenstein and Norway.

B. BASIS FOR THE OPINION

The positive opinions from CHMP are primarily 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. In June 2025, the Group received two GMP certificates issued by the Federal Agency for Medicines and Health Products of Belgium, indicating that the production lines related to HLX14 have met the GMP standards of the EU.

C. ABOUT HLX14

HLX14, which was independently developed by the Company, is a proposed biosimilar to Prolia® (denosumab) 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 May 2024, the marketing authorisation applications (MAAs) for HLX14 was validated by the EMA. In September 2024, the new drug submissions (NDSs) for HLX14 was validated by Health Canada. In October 2024, the biologics license application (BLA) for HLX14 was validated by the U.S. Food and Drug Administration (FDA).

D. MARKET CONDITION

According to the latest data from IQVIA MIDAS™ (provided by IQVIA, 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 2024 was approximately US$7.462 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, 28 July 2025

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. 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.