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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

NEW DRUG APPLICATION (NDA) FOR BIOSIMILAR OF DENOSUMAB HLX14 (RECOMBINANT ANTI-RANKL HUMAN MONOCLONAL ANTIBODY INJECTION) HAS BEEN ACCEPTED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION (NMPA)

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, the New Drug Application (NDA) for a biosimilar of denosumab HLX14 (recombinant anti-RANKL human monoclonal antibody injection) ("**HLX14**") independently developed by the Company, has been accepted by the Center for Drug Evaluation of the National Medical Products Administration (NMPA). The indications involved in the New Drug Application (NDA) encompass all approved and marketed indications for the reference drug 普羅力® (English trade name: Prolia®) in mainland China (excluding Hong Kong, Macau and Taiwan regions of China), including: treatment of osteoporosis in postmenopausal women at high risk of fractures; in postmenopausal women, this product can significantly reduce the risk of vertebral, non-vertebral, and hip fractures; treatment of osteoporosis in men at high risk of fractures; and treatment of glucocorticoid-induced osteoporosis at high risk of fractures.

B. BACKGROUND OF AND BASIS FOR SUBMISSION

The New Drug Application (NDA) of HLX14 was based on the data generated by HLX14 in comparison with its reference drug (Prolia®), which includes analytical similarity studies, nonclinical and clinical comparison studies. These data demonstrated that HLX14 is highly similar to its reference drug in terms of quality, safety and efficacy.

C. ABOUT HLX14

HLX14 is a denosumab biosimilar independently developed by the Company. In Second half year of 2025, two products of HLX14 (trade names in the United States and Europe: BILDYOS® and BILPREVDA®) has been approval for marketing in the United States, the European Union and the United Kingdom, respectively, the approved indications cover all indications for which the originator products (Prolia® and XGEVA®) have been approved in the local market. In September 2024, the new drug submissions (NDSs) for HLX14 were validated by Health Canada.

D. MARKET CONDITION

According to the latest information provided by IQVIA MIDAS™ (provided by IQVIA, which is a provider of professional information and strategic consulting services for the pharmaceutical and healthcare industry globally), the global sales of denosumab worldwide for the year of 2024 was approximately US$7.463 billion.

On Behalf of the Board
Shanghai Henlius Biotech, Inc.
Wenjie Zhang
Chairman

Hong Kong, 2 December 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. 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.