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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)

INSIDE INFORMATION ANNOUNCEMENT

THE UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA) APPROVED TWO PRODUCTS OF HLX14 (DENOSUMAB-NXXP, TRADE NAMES IN THE UNITED STATES: BILDYOS® AND BILPREVDA®) FOR THE TREATMENT OF EIGHT INDICATIONS INCLUDING OSTEOPOROSIS IN CERTAIN POPULATIONS

A. INTRODUCTION

This announcement is made by Shanghai Henlius Biotech, Inc. (the "**Company**") pursuant to Rule 13.09 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") and the Inside Information Provisions (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571, Laws of Hong Kong).

The board of directors of the Company (the "**Board**") is pleased to announce that, recently, the Group has received an approval letter from the United States Food and Drug Administration ("**FDA**"), in which the biologics license application (BLA) for the two products, namely BILDYOS® and BILPREVDA®, was approved by the FDA. The product names are registered in the US in the name of N.V. Organon. The approved indications specifically include:

Product I: BILDYOS® (60mg/mL): for treatment (1) of postmenopausal women with osteoporosis at high risk for fracture; (2) to increase bone mass in men with osteoporosis at high risk for fracture; (3) of glucocorticoid-induced osteoporosis in men and women at high risk for fracture; (4) to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer; (5) to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer; and

Product II: BILPREVDA® (120mg/1.7mL): (1) prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors; (2) treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity; (3) treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

B. BASIS FOR APPROVAL BY THE FDA

The FDA's approval is primarily based on a comprehensive review of a series of comparative study data between HLX14 (denosumab-nxxp) ("**HLX14**") and the reference product, Prolia®, including analytical similarity and comparative clinical studies. These study data provide robust evidence that HLX14 is highly similar to the reference product in terms of quality, safety and efficacy. According to the FDA Guidance for Industry, "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product", HLX14 has been approved for all indications for which the reference products Prolia® and XGEVA® have been authorized in the United States. Meanwhile, manufacturing sites and facilities relating to HLX14 of the Group have undergone the Pre-License Inspection (PLI) by the FDA, and such manufacturing sites and facilities are in compliance with the requirements of FDA's cGMP.

C. ABOUT HLX14

HLX14 is a denosumab biosimilar independently developed by the Company. 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 biologics. Currently, denosumab, the reference biologics 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 were accepted by the European Medicines Agency (EMA), and a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the EMA was received in July 2025. In September 2024, the new drug submissions (NDSs) for HLX14 was validated by Health Canada.

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$7.462 billion.

D. IMPACT ON THE COMPANY

Following the approvals for marketing of BILDYOS® and BILPREVDA®, the Group now has a total of six products approved for marketing overseas, including three in the United States, further deepening its global commercialization efforts. Such approval represents another recognition of the Company's products from the international mainstream market, which will further advance the international footprint of the Company and enhance the international influence of the Company's products.

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

Hong Kong, 1 September 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.