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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

EUROPEAN COMMISSION (EC) APPROVED TWO PRODUCTS OF HLX14 (DENOSUMAB, EUROPEAN TRADE NAMES: BILDYOS® AND BILPREVDA®) FOR THE TREATMENT OF OSTEOPOROSIS IN CERTAIN POPULATIONS AND OTHER INDICATIONS

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 marketing authorisation applications (MAAs) for the two products, namely BILDYOS® and BILPREVDA® have been approved by the European Commission (EC). BILDYOS® and BILPREVDA® are trademarks registered in the European Union ("**EU**") by N.V. Organon. The approval indicates that a centralized marketing authorization in respect of BILDYOS® and BILPREVDA® has been granted in all EU Member States as well as in Iceland, Liechtenstein and Norway (each a European Economic Area (EEA) country). The approved indications encompass all indications for Prolia® and XGEVA® marketed in the EU, specifically including:

Product I:	BILDYOS® (60 mg/mL): (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; and (3) treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture.
Product II:	BILPREVDA® (120 mg/1.7 mL): (1) prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with advanced malignancies involving bone; and (2) 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. BASIS FOR APPROVAL BY THE EUROPEAN COMMISSION (EC)

The approval is primarily based on a comprehensive review of a series of comparative study data between HLX14 (denosumab) ("**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. 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. In addition, in July 2025, HLX14 received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), recommending the approval of the marketing authorisation applications (MAAs) for BILDYOS® and BILPREVDA®.

C. ABOUT HLX14

HLX14 is a denosumab biosimilar independently developed by the Company. In August 2025, BILDYOS® and BILPREVDA® received approval in the United States for the treatment of eight indications including osteoporosis in certain populations, covering all indications for which the original product has been approved in the U.S.. 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 September 2024, the new drug submissions (NDSs) for HLX14 were 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$7.463 billion.

D. IMPACT ON THE COMPANY

Following the approvals for marketing in the United States, the approvals for marketing of BILDYOS® and BILPREVDA® in the EU represents another recognition of the Group'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, 19 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.