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 120 MG (1.7 ML) PER VIAL STRENGTH OF 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**", together with its subsidiaries, the "**Group**") 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 the 120 mg (1.7 mL) per vial strength of a biosimilar of denosumab HLX14 (recombinant anti-RANKL human monoclonal antibody injection) ("**HLX14**") independently developed by the Group, has been accepted by the Center for Drug Evaluation of the National Medical Products Administration (NMPA).

This New Drug Application (NDA) covers the following indications: (1) Bone Metastases from Solid Tumors and Multiple Myeloma: For the treatment of patients with bone metastases from solid tumors or multiple myeloma, to delay or reduce the risk of skeletal-related events (pathological fracture, spinal cord compression, radiation therapy to bone, or surgery to bone); and (2) Giant Cell Tumor of Bone: For the treatment of giant cell tumor of bone that is unresectable or for which surgical resection is likely to result in severe functional impairment, including adults and adolescent patients with a mature skeleton (defined as having at least one mature long bone and body weight ≥45 kg).

B. BACKGROUND OF AND BASIS FOR SUBMISSION

The New Drug Application (NDA) for HLX14 was primarily based on data generated from HLX14 compared with its reference drugs, including analytical similarity studies, non-clinical and clinical comparative studies. These data demonstrated that HLX14 at the 120 mg (1.7 mL) per vial strength 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 Group. In the second half year of 2025, two products of HLX14 (trade names in the United States and Europe: BILDYOS® and BILPREVDA®) were approved for marketing in the United States, the European Union and the United Kingdom, respectively. In March 2026, such products were approved for marketing in Canada (trade names in Canada: BILDYOS® and TUZEMTY®). BILDYOS® is indicated for osteoporosis and all other indications for which the reference products have been approved in the local market, while BILPREVDA®/TUZEMTY® is indicated for cancer-related bone disease and all other indications for which the reference products have been approved in the local market. In December 2025, the New Drug Application (NDA) for HLX14 (60 mg/1.0 mL) was accepted by the Center for Drug Evaluation of the National Medical Products Administration (NMPA).

D. MARKET CONDITION

According to the latest data from IQVIA MIDAS™ (provided by IQVIA, which is a global provider of professional information and strategic consulting services for the pharmaceutical and healthcare industry), the sales value of denosumab worldwide for the year of 2025 was approximately US$8.092 billion.

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

Hong Kong, 11 September 2026

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.