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 HLX11 (PERTUZUMAB, TRADE NAME IN THE UNITED STATES AND EUROPE: POHERDY®) FOR TREATMENTS INCLUDING NEOADJUVANT/ADJUVANT TREATMENT OF HER2-POSITIVE EARLY BREAST CANCER AND METASTATIC BREAST CANCER

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 of the Laws of Hong Kong).

The board of directors of the Company (the "**Board**") is pleased to announce that, recently, the marketing authorization application (MAA) for the Company's independently developed POHERDY® (pertuzumab) 420mg/14mL injection for intravenous use was approved by the European Commission ("**EC**"). POHERDY® is a trademark registered in the European Union ("**EU**") in the name of N.V. Organon. The approved indications include (1) use in combination with trastuzumab and chemotherapy in (i) the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence; and (ii) the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence; and (2) use in combination with trastuzumab and docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease, for all indications of the reference drug approved in Europe. The approval indicates that a centralized marketing authorization in respect of POHERDY® (pertuzumab) has been granted in all EU Member States as well as in Iceland, Liechtenstein and Norway (each a European Economic Area (EEA) country).

B. BASIS FOR APPROVAL BY THE EC

The approval is primarily based on data generated by HLX11 (pertuzumab, trade name in the United States and Europe: POHERDY®) ("**HLX11**") in comparison with the reference drug PERJETA® (pertuzumab), including analytical similarity studies, PK similarity study and clinical comparison studies. These data demonstrated that HLX11 is highly similar to the reference drug PERJETA® in terms of quality, safety and efficacy. 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 HLX11 have met the GMP standards of the EU. In addition, in February 2026, HLX11 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 MAA for POHERDY®.

C. ABOUT HLX11

HLX11 is a pertuzumab biosimilar independently developed by the Company, mainly used for treatments including neoadjuvant/adjuvant treatment of HER2-positive early breast cancer and metastatic breast cancer. 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 HLX11 globally except for mainland China, Hong Kong, Macau and Taiwan regions. In December 2024, the new drug application (NDA) for HLX11 was accepted by the National Medical Products Administration (NMPA). In May 2025, the new drug submission (NDS) for HLX11 was accepted by Health Canada. In November 2025, the biologics license application (BLA) for HLX11 was approved by the United States Food and Drug Administration (FDA).

According to 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 pertuzumab products worldwide for the year of 2025 was approximately US$2.978 billion.

D. IMPACT ON THE COMPANY

Following the approval for marketing in the United States, the approval for marketing of POHERDY® 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. The Group will work with its collaborator Organon LLC to commercialize the product in certain regions once conditions are met.

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

Hong Kong, 28 April 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.