

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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

PERTUZUMAB BIOSIMILAR HLX11 (RECOMBINANT ANTI-HER2 DOMAIN II HUMANIZED MONOCLONAL ANTIBODY INJECTION) RECEIVED POSITIVE OPINION FROM THE COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP) OF THE EUROPEAN MEDICINES AGENCY (EMA)

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.

Reference is made to the announcement of the Company dated 28 March 2025 in relation to that the marketing authorisation application (the **“MAA”**) for HLX11, a proposed Perjeta® (pertuzumab) biosimilar candidate (recombinant anti-HER2 domain II humanized monoclonal antibody injection) (**“HLX11”**) independently developed by the Company for the (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 docetaxelin 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 have been validated by the European Medicines Agency (**“EMA”**).

The board of directors of the Company (the **“Board”**) is pleased to announce that, recently, HLX11 received positive opinion from the Committee for Medicinal Products for Human Use (**“CHMP”**) of the EMA, recommending the approval of the MAA of HLX11. The opinion from CHMP will be submitted to the European Commission (**“EC”**), then the EC will issue final review decision based on such opinion within the next two to three months. If approved by the EC, centralised marketing authorisation in respect of HLX11 will be valid in all EU Member States as well as European Economic Area (EEA) countries Iceland, Liechtenstein and Norway.

B. BASIS FOR THE OPINION

The positive opinion from CHMP is primarily based on data generated by 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.

C. ABOUT HLX11

HLX11 is a pertuzumab biosimilar independently developed by the Company. 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 March 2025, the marketing authorisation application (MAA) for HLX11 was accepted by the European Medicines Agency (EMA). 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).

D. MARKET CONDITION

According to the latest data from 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 2024 was approximately US\$3.304 billion.

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

Hong Kong, 27 February 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.