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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)

VOLUNTARY ANNOUNCEMENT

THE UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA) APPROVED HLX11 (PERTUZUMAB-DPZB, TRADE NAME IN THE UNITED STATES: 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**") 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 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 POHERDY® (pertuzumab-dpzb) 420mg/14mL (30mg/mL) injection for intravenous use was approved by the FDA. POHERDY® is a trademark registered in the United States in the name of N.V. Organon. The approved indications including (1) use in combination with trastuzumab and docetaxel for the treatment of adults with HER2-positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease; (2) use in combination with trastuzumab and chemotherapy as: (i) neoadjuvant treatment of adults with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer; and (ii) adjuvant treatment of adults with HER2-positive early breast cancer at high risk of recurrence.

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 HLX11 (pertuzumab-dpzb) ("**HLX11**") and the reference product, Perjeta®, including analytical similarity and comparative clinical studies. These study data provide robust evidence that HLX11 is highly similar to the reference product in terms of quality, safety and efficacy. HLX11 has been approved for all indications of the reference product, Perjeta®, as approved in the United States. Meanwhile, manufacturing sites and facilities relating to HLX11 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 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 commercialize 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 authorization 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.

According to the latest data from IQVIA MIDAS™ (provided by IQVIA, which is 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.

D. IMPACT ON THE COMPANY

Following the approval for marketing of POHERDY®, the Group now has a total of seven products approved for marketing overseas, including four in the United States. 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. The Group will collaborate with its partner Organon LLC to promote local commercial sales once conditions are met.

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

Hong Kong, 14 November 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.