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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

THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION APPROVED HANBEIYOU (PERTUZUMAB INJECTION) FOR THE NEOADJUVANT/ ADJUVANT TREATMENT OF HER2-POSITIVE EARLY BREAST CANCER AND FOR THE TREATMENT OF 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, Laws of Hong Kong).

The board of directors of the Company (the “**Board**”) is pleased to announce that, recently, the New Drug Application (NDA) for HANBEIYOU (pertuzumab injection) (“**HANBEIYOU**”) independently developed by the Company was approved by the National Medical Products Administration (“**NMPA**”). The approved indications specifically include: (1) early breast cancer: this product, in combination with trastuzumab and chemotherapy, is for (i) the neoadjuvant treatment for patients with HER2-positive, locally advanced, inflammatory, or early 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) the adjuvant treatment for patients with HER2-positive early breast cancer with high risk of recurrence; and (2) metastatic breast cancer: pertuzumab, in combination with trastuzumab and docetaxel, is indicated for patients with HER2-positive, metastatic, or unresectable locally recurrent breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic breast cancer, covering all indications approved in the Chinese Mainland for the reference pertuzumab injection.

The approval is primarily based on a comprehensive review of a series of comparative study data between HANBEIYOU and reference pertuzumab, including analytical similarity study, pharmacokinetic similarity study and comparative clinical study. These study data have demonstrated that HANBEIYOU is highly similar to the reference pertuzumab in terms of quality, safety and efficacy.

B. BASIC INFORMATION ABOUT THE DRUG

Common Name:	Pertuzumab injection
Trade Name:	HANBEIYOU
Dosage Form:	Injection
Specification:	420 mg (14 ml)/vial
Registration Category:	Therapeutic biological products
Drug Manufacturer:	Shanghai Henlius Biologics Co., Ltd.
Drug Approval Number:	Guo Yao Zhun Zi S20260034

C. ABOUT HANBEIYOU

HANBEIYOU (Pertuzumab Injection, trade name in the Chinese Mainland: HANBEIYOU, trade name in the United States: POHERDY®, project code: HLX11) is a pertuzumab biosimilar independently developed by the Company, mainly used for the neoadjuvant/adjuvant treatment of HER2-positive early breast cancer and for the treatment of metastatic breast cancer. In May 2025, the New Drug Submissions (NDSs) for HANBEIYOU were accepted by Health Canada. In June 2025, the Group received two GMP certificates issued by the Federal Agency for Medicines and Health Products of Belgium, demonstrating that the production lines related to HANBEIYOU comply with EU GMP standards. In November 2025, the Biologics License Application (BLA) for HANBEIYOU was approved by the U.S. Food and Drug Administration (FDA). In April 2026, the marketing authorization application (MAA) for HANBEIYOU was approved by the European Commission (EC).

D. MARKET CONDITION

According to the information provided by IQVIA MIDAS™ (IQVIA is a global provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry), the sales revenue of pertuzumab product in the Chinese Mainland was approximately RMB2.728 billion in 2025.

E. IMPACT ON THE COMPANY

The approval for marketing of HANBEIYOU in the Chinese Mainland has enriched the Group's commercial products in the Chinese breast cancer market. HANBEIYOU will provide more treatment options for Chinese patients with HER2-positive breast cancer, and it is also expected to strengthen the Group's leading position in the field of breast cancer treatment in China.

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

Hong Kong, 29 May 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.