

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
HANBEIYOU (PERTUZUMAB INJECTION)
PASSING GMP COMPLIANCE INSPECTION**

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, Shanghai Henlius Biologics Co., Ltd.* (上海復宏漢霖生物醫藥有限公司), a wholly-owned subsidiary of the Company, received the “Notice of GMP Compliance Inspection for Pharmaceuticals” issued by Shanghai Medical Products Administration, pursuant to which the drug substance (DS) east line, drug product (DP) production line and packaging line of HANBEIYOU (pertuzumab injection) in biopharmaceutical production base of the Company in Songjiang district, Shanghai (the “**Songjiang First Plant**”) successfully passed the compliance inspection for the Good Manufacturing Practice conducted by Shanghai Medical Products Administration.

B. OVERVIEW OF ON-SITE INSPECTION

Name of enterprise:	Shanghai Henlius Biologics Co., Ltd.
Production address:	Building 1, No. 182 Wenjun Road, Songjiang District, Shanghai
Product subject to inspection:	HANBEIYOU (Pertuzumab Injection)
Scope of inspection:	Drug substance (DS) east line and drug product (DP) production line and packaging line
Conclusion of inspection:	Complying with the requirements

C. ABOUT HANBEIYOU (PERTUZUMAB INJECTION)

HANBEIYOU (Pertuzumab Injection, trade name in Chinese Mainland: HANBEIYOU, trade name in the United States and Europe: POHERDY®, project code: HLX11) (“**HANBEIYOU**”) is a pertuzumab biosimilar independently developed by the Company, which is mainly used for treatments including neoadjuvant/adjuvant treatment of HER2-positive early breast cancer and metastatic breast cancer. In May 2025, the New Drug Submission (NDS) for HANBEIYOU was 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). In May 2026, the New Drug Application (NDA) for HANBEIYOU was approved by the National Medical Products Administration (NMPA).

According to IQVIA CHPA (IQVIA is a global provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry), the sales revenue of pertuzumab injection in the Chinese Mainland (excluding Hong Kong, Macao and Taiwan region of China, same as below) was approximately RMB2.728 billion in 2025.

D. IMPACT ON THE COMPANY

The completion of GMP compliance inspection of HANBEIYOU demonstrates that it has established a quality management system in full compliance with Chinese GMP regulations. The Company’s Songjiang First Plant is eligible to conduct commercial production of HANBEIYOU in the Chinese Mainland.

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

Hong Kong, 17 June 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.

* for identification purposes only