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

HLX02 (TRASTUZUMAB-STRF, PROPRIETARY NAME IN THE UNITED STATES: HERCESSI™) FOR THE TREATMENT OF ADJUVANT BREAST CANCER, METASTATIC BREAST CANCER AND METASTATIC GASTRIC CANCER APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA)

A. INTRODUCTION

This announcement is made by Shanghai Henlius Biotech, Inc. (the "**Company**", together with its subsidiaries, the "**Group**") 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).

Reference is made to the announcements of the Company dated 30 September 2020 and 4 January 2021 in relation to a license agreement entered into between the Company and Intas Pharmaceuticals Limited ("**Intas**"), pursuant to which, the Company granted Intas and its affiliates an exclusive license to commercialize HLX02 (trastuzumab for injection) in the United States and Canada. In February 2023, the Biologic License Application (BLA) for HLX02 (trastuzumab for injection) with a strength of 150mg/vial, which was submitted by our business partner in the United States, Accord BioPharma Inc. ("**Accord**", an affiliate of Intas), had been accepted for review by the United States Food and Drug Administration ("**FDA**").

The board of directors of the Company (the "**Board**") is pleased to announce that, recently, Accord has received an approval letter from the FDA for HLX02 (trastuzumab-strf) with a strength of 150mg/vial, indicated for (1) adjuvant treatment of HER2-overexpressing breast cancer; (2) the treatment of HER2-overexpressing metastatic breast cancer; and (3) the treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. The proprietary name approved for HLX02 in the United States is HERCESSI™. Accordingly, HLX02 (trastuzumab for injection) is the first product of the Company approved by the FDA for marketing in the United States.

B. BASIS FOR APPROVAL BY THE FDA

The FDA approval is primarily based on the review of a series of study data of HLX02 (trastuzumab for injection), known as HANQUYOU in mainland China (excluding Hong Kong, Macau and Taiwan regions, same as below), versus the reference product, Herceptin®, including analytical similarity and clinical studies, etc. These data prove that HLX02 (trastuzumab for injection) is highly similar to the reference product Herceptin® in terms of quality, safety and efficacy. Meanwhile, manufacturing sites and facilities relating to HLX02 (trastuzumab for injection) of the Group have undergone the Pre-License Inspection (PLI) by the FDA, and such manufacturing sites and facilities meet the FDA's cGMP.

C. ABOUT HLX02 (TRASTUZUMAB FOR INJECTION)

HLX02 (trastuzumab for injection, trade name in mainland China: HANQUYOU; trade name in Europe: Zercepac®; proprietary name in the United States: HERCESSI™) is a monoclonal antibody biosimilar independently developed by the Company in accordance with the guidelines for biosimilar in the mainland China, the EU and the United States with triple approvals in mainland China, the EU and the United States, for the adjuvant treatment of HER2-positive breast cancer and the treatment of HER2-positive breast cancer and gastric cancer. For mainland China, HANQUYOU (trastuzumab for injection) with a strength of 150mg/vial was approved by the National Medical Products Administration (the "**NMPA**") for marketing in August 2020 and its supplemental new drug application (sNDA) for new strength of 60mg/vial was also approved by the NMPA in August 2021. For oversea markets, Zercepac® (trastuzumab for injection) with a strength of 150mg/vial was approved by the European Commission ("**EC**") for marketing in the EU in July 2020 and its sNDA for strengths of 60mg/vial and 420mg/vial was also approved by the EC in 2021. The exclusive right to commercialize Zercepac® in Europe was granted to Accord Healthcare Limited, a business partner of the Company. In addition to the countries and regions aforementioned and the approval in the United States, HLX02 (trastuzumab for injection) was also approved for marketing in Australia, Cambodia, Singapore, Argentina, Brazil and other countries, respectively, through the promotion of the Company's various business partners.

As of the date of this announcement, in addition to the Company's HLX02 (trastuzumab for injection), trastuzumab that has been marketed globally include Herceptin® by Roche, Kanjinti® by Amgen and Trazimera® by Pfizer, along with others. According to the information provided by IQVIA MIDAS™ (IQVIA is a world provider of professional medical and health information and strategic consultation), global sales of trastuzumab in 2023 were approximately US$3.594 billion.

D. IMPACT ON THE COMPANY

HLX02 (trastuzumab for injection) is the first product of the Company approved by FDA for marketing and commercialization in the United States. The approval by FDA will further advance the international footprint of the Company and enhance the international influence of the Company's products.

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

Hong Kong, 26 April 2024

As at the date of this announcement, the board of directors of the Company comprises Mr. Wenjie Zhang as the chairman and executive director, Mr. Jun Zhu as the executive director, Mr. Qiyu Chen, Mr. Yifang Wu, Ms. Xiaohui Guan, Mr. Deyong Wen and Dr. Xingli Wang as the non-executive directors, and Mr. Tak Young So, Dr. Lik Yuen Chan, Dr. Guoping Zhao and Dr. Ruilin Song as the independent non-executive directors.